California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Legislation and Regulation Committee Report
April 8, 2003

Steve Litsey, Chair
Andrea Zinder, Member

FOR ACTION

Recommendation 1

That the Board of Pharmacy adopt the proposed regulation to revise the citation and fine process to permit the executive officer to issue citations and fines (Sections 1775 et seq., see attachment A for the proposed text).

Discussion

Notice of proposed action published on February 21, 2003 and the 45-day comment period closed on April 7, 2003. The regulation was noticed without a regulation hearing and no hearing was requested by any interested party. The board received no comments during the 45-day written comment period.

The Joint Legislative Sunset Review Committee approved a recommendation on April 7, 2003 for the board to revise its citation and fine process to designate the executive officer as the issuing authority for citations and fines to make Board of Pharmacy practices consistent with other boards in the Department of Consumer Affairs. This regulation would implement that recommendation.

Recommendation 2

That the board adopt the proposed sterile compounding guidelines upon the close of the regulation hearing. (see Regulation Hearing for proposed language and summary of comments)

Recommendation 3

That the board sponsor the addition of section 4106 in the annual omnibus bill.

Discussion

The committee is suggesting this language to reduce workload associated with providing license verifications to interested parties. By allowing license verifications from the board's to be accepted by those needing to verify licensure, fewer verification requests will be submitted to board staff. This is particularly of concern for wholesalers wishing to ship to newly licensed pharmacies.

Add Section 4106 to the Business and Professions Code.

4106. For purposes of license verification, a person may rely upon a printout from the board's web site, that includes the license issuance and expiration dates, of any board-issued license.

Recommendation 4

That the board adopt an oppose unless amended position on Assembly Bill 103.
(see attachment B for the analysis)

Discussion

The committee is sympathetic with the desire to decrease drug costs and open drug marketing practices to greater public scrutiny. However, the bill as currently drafted imposes a significant new programmatic responsibility on the board without providing additional resources to implement this new program. In addition, the bill requires substantial amendments to clarify the program requirements and to allow for effective implementation. Accordingly, the committee recommends an oppose unless amended position. The recommended amendments would provide for either General Fund or non-profit financial support of the program and makes a number of other changes required for effective program implementation. The proposed amendments are attached to the analysis on this bill.

Recommendation 5

That the board adopt a support position on Assembly Bill 261.
(see attachment C for the analysis)

Discussion

The committee recommends a support position on Assembly Bill 261. The public health threat posed by backroom clinics warrants granting prosecutors the opportunity to charge these cases as felonies.

Recommendation 6

That the board adopt a support if amended position on Assembly Bill 521.
(see attachment D for the analysis)

Discussion

The committee recommends a support if amended position on Assembly Bill 521 because it will provide consumers with valuable drug information in an accessible format. The committee recommends amendments that would specify a minimum type size and defer implementation to allow adequate time for pharmacies to make the required system changes. The proposed amendments are attached to the analysis on this bill.

Recommendation 7

That the board adopt a support position on Assembly Bill 746.
(see attachment E for the analysis)

Discussion

The committee recommends a support position on Assembly Bill 746 because it grants the board greater authority to take disciplinary action against licensee convicted of Medi-Cal fraud.

Recommendation 8

That the board adopt a support position on Assembly Bill 1363.
(see attachment F for the analysis)

Discussion

The committee recommends a support position on Assembly Bill 1363 because it will expand access to clean needles and syringes. The board has supported such legislation in the past based on the public health benefit of these proposals.

Recommendation 9

That the board adopt a support position on Assembly Bill 1460.
(see attachment G for the analysis)

Discussion

The committee recommends a support position on Assembly Bill 1460 because it intends to provide pharmacists with greater ability to manage patients drug therapy.

No Action Required

SB 151 (Burton) repeals the triplicate and substitutes a forgery and counterfeit resistant prescription form. The board supports this legislation based on longstanding policy favoring the repeal of the triplicate requirement for Schedule II controlled substance prescriptions. (see attachment H for the text of the bill)

Recommendation 10

That the board adopt a support if amended position on Senate Bill 175.
(see attachment I for the analysis)

Discussion

The committee recommends a support if amended position on Senate Bill 175 because it clarifies the board's regulatory authority over veterinary drugs. The recommended amendments make technical changes to the bill.

No Action Required

SB 361 (Figueroa) is the legislation introduced to be the vehicle for the Board of Pharmacy sunset extension and to contain statutory recommendations approved by the Joint Legislative Sunset Review Committee. (see attachment J for text of the legislation)

Recommendation 11

That the board adopt a support if amended position on Senate Bill 393.
(see attachment K for the analysis)

Discussion

The committee recommends a support if amended position on Senate Bill 393 because it implements much of the board's existing policy supporting tech check tech in hospitals. The committee seeks an amendment specifying the training required for pharmacy technicians in tech check tech programs in statute.

Recommendation 12

That the board adopt an oppose unless amended position on Senate Bill 545.
(see attachment L for the analysis)

Discussion

The committee recommends an oppose unless amended position on Senate Bill 545 because it deletes the training requirement for dispensing emergency contraception under protocol and inappropriately limits pharmacists' judgment regarding appropriate patient consultation. The committee also expressed concern that the bill fails to recognize the practice of pharmacy outside the four walls of a pharmacy. The committee recommends amendments restoring the training requirements and deleting the restriction on patient consultation.

Recommendation 13

That the board adopt a support position on Senate Bill 774.
(see attachment M for the analysis)

Discussion

The committee recommends a support position on Senate Bill 774 because it will expand access to clean needles and syringes. The board has supported such legislation in the past based on the public health benefit of these proposals.

NO ACTION

The Legislation and Regulation Committee reviewed the following bills and recommended that the board not take a position. Although the committee is recommending no action, the board can discuss and take an action on any of these legislative proposals. (see attachment N for analyses and text of the following bills)

AB 57 (Bates)
Subject: MDMA

AB 186 (Correa)
Subject: Optometrists

AB 1196 (Montanez)
Subject: Nurse Practitioners

SB 292 (Speier)
Subject: Prescription Labels

SB 490 (Alpert)
Subject: Emergency Contraception

SB 506 (Sher)
Subject: Animal Drugs

Pending Regulations

The following regulations were approved by the Office of Administrative Law for review and became effective on March 12, 2003.

Section 1717 (e) – Delivery of Medications
Section 1720.4 – Foreign Graduates
Section 1745 – Partial Filling of Schedule II Prescriptions

For your information, an update on current board rulemaking activity is attached to this report (Attachment O).

Quarterly Status Report on Committee Goals for 2002-03

For your information, an update of the Committee's progress in accomplishing its strategic objectives is attached to this report (attachment P).

Proposed Objectives for 2003/04

The proposed objectives will be discussed during the board's strategic planning session. Please review for clarity and priority. (attachment Q)

Meeting Summary for March 27, 2003

For your information the minutes from the March 27, 2003 meeting of the Legislation and Regulation Committee meeting is attached to this report (Attachment R). The committee scheduled its next meeting for June 25, 2003 at 9:00 a.m.

Attachment A

Board of Pharmacy
Amendments to Title 16, Division 17 of the
California Code of Regulations

Article 9 --Citations and Fines

Amend Section 1775
§1775. Issuing Citations ~~and Fines.~~

(a) ~~A committee of the board~~ The executive officer or his/her designee may issue a citation ~~citations~~ which may contain either or both an administrative fine and an order of abatement ~~containing orders of abatement and fines~~ for:

(1) A violation of the Pharmacy Law (Business and Professions Code 4000 et seq.).

(2) A violation of a regulation adopted by the board.

(3) A violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

(4) Defaulting on a United States Department of Health and Human Services education loan.

(5) A violation of other statutes or regulations for which the board may issue a citation.

any violation of the Pharmacy Law or regulations adopted pursuant thereto. For the purposes of this article, "committee of the board" means a committee of board members appointed by the board president to consider investigations of alleged violations.

(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the individual personally or by certified mail.

(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. If a hearing is not requested pursuant to this article, payment of any fine shall not constitute an admission of the violation charged.

(d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A person or entity shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that hearing. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code, Section 56.36 of the Civil Code. Reference: Sections 125.9, 148, and 685 ~~and 148~~, Business and Professions Code, Section 56.36 of the Civil Code.

Add Section 1775.1
§1775.1. Amount of Fines

(a) The fine for violating the Pharmacy Law or regulations adopted pursuant thereto shall not exceed the amount specified in Section 125.9 of the Business and Professions Code, except for a fine issued pursuant to Section 4067 or Section 4127.4 of the Business and Professions Code.
(b) The fine for violating the Confidentiality of Medical Information Act shall not exceed the amount specified in Section 56.36 of the Civil Code.
(c) The fine for defaulting on a United States Department of Health and Human Services education loan shall not exceed $2,500.
(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code, Section 56.36 of the Civil Code. Reference: Sections 125.9, 148, 685, 4067 and 4127.4 Business and Professions Code, Section 56.36 of the Civil Code.

Repeal Section 1775.15.
§1775.15. Executive Officer, Citations.

~~(a) The executive officer may issue citations for violations of the following:~~
~~(1) Article 8 of the Pharmacy Law (Commencing with Business and Professions Code Section 4130) and any regulations relating to medical device retailers.~~
~~(2) Article 9 of the Pharmacy Law (Commencing with Business and Professions Code Section 4140) and any regulations relating to hypodermic needles and syringes.~~
~~(3) Article 11 of the Pharmacy Law (Commencing with Business and Professions Code Section 4160) and any regulations relating to wholesalers and manufacturers.~~
~~(4) Article 13 of the Pharmacy Law (Commencing with Business and Professions Code Section 4180) and any regulations relating to nonprofit or free clinics.~~
~~(5) Article 14 of the Pharmacy Law (Commencing with Business and Professions Code Section 4190) and any regulations relating to surgical clinics.~~
~~(6) Article 15 of the Pharmacy Law (Commencing with Business and Professions Code Section 4196) and any regulations relating to veterinary food-animal drug retailers.~~
~~(7) Article 17 of the Pharmacy Law (Commencing with Business and Professions Code Section 4230) and any regulations relating to continuing education.~~
~~(8) Section 1708.2 of Title 16 of the California Code of Regulations.~~
~~(b) The executive officer may also issue citations, in accordance with Section 148 of the Business and Professions Code, against any person (as defined in Section 302 of the Code) who is performing or who has performed services for which licensure is required under the Pharmacy Law or regulations adopted pursuant thereto. Each citation issued under this section shall contain an order of abatement. The sanction authorized under this section shall be separate from and in addition to any other civil or criminal remedies.~~
(c) In addition to the formal appeals process contained in Business and Professions Code Section 125.9(b)(4) and Section 1775.4(a) of Title 16 of the California Code of Regulations, an intermediate appeal of any citation issued by the executive officer shall be heard by a committee

of the board where the appellant appears in person before the committee. Requests for a hearing by a committee of the board must be submitted within 14 days of receipt of the citation. A committee of the board may either affirm, modify (but not increase) or dismiss the citation, including any administrative fine or order of abatement.

Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

Amend Section 1775.2.
§1775.2. ~~Amount of Fines and~~ Factors Considered.

In no event shall a fine issued pursuant to Section 1775 exceed $2,500.
In his/her or its discretion, the executive officer or a committee of the board may issue a citation with an order of abatement without levying a fine.
In assessing the amount of an administrative fine, except violations of the Confidentiality of Medical Information Act and when assessing a fine pursuant to Business and Professions Code section 685, the ~~executive officer or a committee of the board shall give due consideration to~~ the following factors shall be considered:

(a) The gravity of the violation.
(b) The good or bad faith of the cited person or entity.
(c) The history of previous violations.
~~(d) Evidence that the violation was or was not willful.~~
(e) The extent to which the cited person or entity has cooperated with the board's investigation.
(f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
(g) Other matters as may be appropriate.
(h) The number of violations found in the investigation.

Authority cited: Sections 125.9, 148, 685, and 4005, Business and Professions Code, Section 56.36, Civil Code. Reference: Sections 125.9, ~~and~~ 148 and 685, Business and Professions Code, Section 56.36, Civil Code.

Amend Section 1775.3
§1775.3. Compliance with Orders of Abatement.

(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request, from the board, an extension of time in which to complete the correction ~~from the board~~. Such a request shall be in writing and shall be made within the time set forth for abatement.
(b) When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement. An order of abatement shall either be personally served or mailed by certified mail. ~~The time allowed for the abatement of a violation shall begin when the order of abatement is final and has been served~~

~~or received. Such failure~~ Failure to comply with an order of abatement shall constitute a ground for revocation or suspension of the license, permit, or registration.
Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

~~Authority cited: Sections 125.9, 148, 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.~~

§1775.4. Contested Citations.

~~(a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act (Government Code 11340 et seq.).~~ Government Code Section 11500 et seq~~.~~
(b) In addition to requesting a hearing, as provided for in subdivision (a) ~~subsection (b)(4) of Section 125.9 of the Business and Professions Code~~, the person or entity cited may, within 14 calendar days after service of a citation ~~by the board inspector~~, submit a written request for an informal office conference. ~~The time allowed for the request shall begin the first day after the citation has been received by the cited person or entity.~~ The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request.~~, a supervising inspector or board member(s).~~
(c) The executive officer or his/her designee ~~, supervising inspector or board member(s)~~ shall hold an informal office conference upon request as provided for in subdivision (b) ~~section 1775.4(b)~~ with the person or entity cited ~~and/or his/her or its~~ and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee ~~, supervising inspector or board member(s)~~ may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee ~~, supervising inspector or board member(s)~~ shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.
(d) The person or entity cited does not waive their ~~his/her or its~~ request for a hearing to contest a citation by requesting an office conference after which the citation is affirmed by the executive officer or his/her designee.~~, supervising inspector or board member(s).~~ If the citation is dismissed after the office conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation. ~~in accordance with subsection (b)(4) of Section 125.9 of the Business and Professions Code.~~

Authority cited: Sections 125.9, 148, 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

Article 9.6. Citation and Fine -- Patient Privacy Violations

Repeal Section 1777
§1777. Authority to Issue Citations.

~~(a) A committee of the board may issue citations against a licensee containing orders of abatement and fines for the disclosure of medical information in violation of the Confidentiality of Medical Information Act (Commencing with Section 56 of the Civil Code). Any citation issued for the willful disclosure of medical information for financial gain shall be accompanied by an order of abatement that requires the disgorgement of any proceeds or other consideration obtained as a result of the violation. For the purposes of this article, "committee of the board" means a committee of board members appointed by the board president to consider investigations of alleged violations.~~
~~(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the licensee personally or by certified mail.~~
~~(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. Payment of any fine shall not constitute an admission of the violation charged.~~
~~(d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A licensee shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that meeting. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Repeal Section 1777.1
§1777.1. Amount of Fines for Violations by Pharmacists.

~~(a) Any pharmacist, who negligently discloses medical information in violation of the provisions the Confidentiality of Medical Information Act shall be subject, irrespective of the amount of damages suffered by the patient as a result of that violation, to an administrative fine not to exceed two thousand five hundred dollars ($2,500) per violation.~~
~~(b) A pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act shall be subject on a first violation,~~

~~for an administrative fine not to exceed two thousand five hundred dollars ($2,500) per violation, or on a second violation for an administrative fine not to exceed ten thousand dollars ($10,000) per violation, or on a third and subsequent violation for an administrative fine not to exceed twenty-five thousand dollars ($25,000) per violation.~~
~~(c) A pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act for financial gain shall be liable on a first violation, for an administrative fine not to exceed five thousand dollars ($5,000) per violation, or on a second violation for an administrative fine not to exceed twenty-five thousand dollars ($25,000) per violation, or on a third and subsequent violation for an administrative fine not to exceed two hundred fifty thousand dollars ($250,000) per violation.~~
~~(d) Nothing in this subdivision shall be construed as authorizing an administrative fine under both this section and section 1777.2 for the same violation.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Repeal Section1777.2
§1777.2. Amount of Fines for Violations by Non-Professional Licensees.

~~(a) Any person or entity licensed by the board, other than a pharmacist, that negligently discloses medical information in violation of the provisions the Confidentiality of Medical Information Act shall be subject, irrespective of the amount of damages suffered by the patient as a result of that violation, to an administrative fine not to exceed two thousand five hundred dollars ($2,500) per violation.~~
~~(b) Any person or entity licensed by the board, other than a pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act shall be subject to an administrative fine not to exceed twenty-five thousand dollars ($25,000) per violation.~~
~~(c) Any person or entity licensed by the board, other than a pharmacist, who knowingly or willfully obtains or uses medical information in violation of the Confidentiality of Medical Information Act for the purpose of financial gain shall be liable for an administrative fine not to exceed two hundred fifty thousand dollars ($250,000) per violation.~~
~~(d) Nothing in this subdivision shall be construed as authorizing an administrative fine or civil penalty under both this section and section 1777.1 for the same violation.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Repeal Section 1777.3
§1777.3. Factors Considered in Assessing Fines.

~~In assessing the amount of an administrative fine pursuant to section 1777.2, the committee of the board shall consider any one or more of the relevant circumstances presented by any of the parties to the case including, but not limited to, the following:~~

~~(1) Whether the respondent has made a reasonable, good faith attempt to comply with the Confidentiality of Medical Information Act (Civil Code Section 56 et seq.).~~

~~(2) The nature and seriousness of the misconduct.~~
~~(3) The harm to the patient.~~
~~(4) The number of violations.~~
~~(5) The persistence of the misconduct.~~
~~(6) The length of time over which the misconduct occurred.~~
~~(7) The willfulness of the defendant's misconduct.~~
~~(8) The defendant's assets, liabilities, and net worth.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Repeal Section 1777.4
§1777.4. Compliance With Orders of Abatement.

~~(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request an extension of time in which to complete the correction from the board. Such a request shall be in writing and shall be made within the time set forth for abatement.~~
~~(b) An order of abatement shall either be personally served or served by certified mail. The time allowed for the abatement of a violation shall begin when the order of abatement is issued.~~
~~(c) Failure to abate the violation within the time frame specified in the order of abatement, shall constitute a ground for revocation or suspension of the license, permit, or registration. When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement.~~
~~(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Sections 125.9 and 4301, Business and Professions Code.

Repeal Section 1777.5
§1777.5. Contested Citations.

~~Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals under this article shall be conducted in accordance with Section 4300(e) of the Business and Professions Code.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Article 9.8. Citation and Fine -- Internet Dispensing Violations

Repeal Section 1778
§1778. Authority to Issue Citations.

~~(a) A committee of the board may issue citations containing orders of abatement and fines for dispensing or furnishing, or causing to be dispensed or furnished, dangerous drugs or dangerous devices, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination, or if the person or entity did not act in accordance with Section 1761. For the purposes of this article, "committee of the board" means a committee of board members appointed by the board president to consider investigations of alleged violations.~~
~~(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the licensee personally or by certified mail.~~
~~(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the citation and/or fine, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. Payment of any fine shall not constitute an admission of the violation charged.~~
~~(d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A licensee shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that meeting. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4067, Business and Professions Code.

Repeal Section 1778.1
§1778.1. Factors Considered in Assessing Fines.

~~Fines issued pursuant to this article shall not exceed $25,000 per violation. In assessing the amount of an administrative fine, the committee of the board shall give due consideration to the following factors:~~

~~(a) The gravity of the violation.~~
~~(b) The good or bad faith of the cited person or entity.~~
~~(c) The history of previous violations.~~
~~(d) Evidence that the violation was or was not willful.~~
~~(e) The extent to which the cited person or entity has cooperated with the board's investigation.~~

~~(f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.~~
~~(g) Other matters as may be appropriate.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4067, Business and Professions Code.

Repeal Section 1778.2
§1778.2. Compliance With Orders of Abatement.

~~(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request an extension of time in which to complete the correction from the board. Such a request shall be in writing and shall be made within the time set forth for abatement.~~
~~(b) An order of abatement shall either be personally served or served by certified mail. The time allowed for the abatement of a violation shall begin when the order of abatement is issued.~~
~~(c) When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement. Such failure shall constitute a ground for revocation or suspension of the license, permit, or registration.~~
~~(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 125.9 and 4067, Business and Professions Code.

Repeal Section 1778.3
§1778.3. Contested Citations.

~~Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals under this article shall be conducted in accordance with Section 4300(e) of the Business and Professions Code.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4067, Business and Professions Code.

Attachment B

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 103 **VERSION: AS AMENDED MARCH 25, 2003**

AUTHOR: REYES **SPONSOR: CALPIRG**

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

SUBJECT: DRUG MARKETING

Existing Law:

1) Requires pharmacists, pharmacies, and wholesalers to be licensed by the board.

2) Requires pharmaceutical manufacturers to be licensed by the Food and Drug Administration (FDA) or the Department of Health Services (DHS).

This Bill:

1) Requires pharmaceutical manufacturers and wholesale distributors to report the value of gifts provided to health professionals (identified by name) to the board annually beginning January 1, 2005. (B&P 4168)

2) Requires that the report of gifts be made in a manner specified by the board. (B&P 4168)

3) Requires the board to file a report with the Legislature annually, on or before March 1, 2006 regarding the data submitted. (B&P 4168)

4) Requires pharmaceutical manufacturing companies to designate a responsible party to the board. (B&P 4168)

5) Prohibits the board from disclosing any information designated by the manufacturer as a "trade secret." (B&P 4168)

6) Exempts the following gifts from the reporting requirement (B&P 4168):

   a. Drug samples.
   b. Reasonable compensation/reimbursement of expenses for participation in a clinical trial.
   c. Gifts of less than $25.

7) Provides for a civil penalty of $10,000 per occurrence for each violation of this bill. (B&P 4168)

8) Defines "pharmaceutical manufacturing company" as an entity engaged in the production, preparation, propagation, compounding, conversion or processing of dangerous drugs. Further defines "pharmaceutical manufacturing company" as an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. (B&P 4168)

Comment:

1) Author's Intent. The author is attempting to address the linkage between drug manufacturer marketing activity and prescribing behavior. The author cites both a Kaiser Family Foundation study that indicates 62% of doctors are accepting gifts from drug manufacturers and a study published in the Journal of the American Medical Association that found linkages between such marketing activity and prescriber behavior. The bill adopts a sunshine approach to reducing the influence of drug marketing on prescribing behavior. The bill is modeled on California's Political Reform Act that requires the reporting and publication of any gifts received by elected officials and other decision makers in state government. The author's office expects that the public sharing of this information will reduce the number and value of gifts doctors accept from drug manufacturers. The author notes that the Department of Health and Human Services, Office of the Inspector General is reviewing drug marketing practices in light of federal laws relating to kickbacks and is expected to issue an opinion in April. That opinion may eliminate the need for this bill.

2) Suggested Amendments. The Legislation and Regulation Committee (committee) recommends an oppose unless amended position. The committee suggests amendments to provide a funding source for the bill and to ease the implementation of the bill's requirements by the board. Draft amendments to this effect are attached for the board's consideration. Most notably, these amendments specify that the bill be implemented to the extent funds are appropriated from the General Fund or to the extent that funds are provided by a non-profit agency. The amendments also extend the implementation date for the bill to allow the board adequate time to design a data system to collect and analyze this data, complete a feasibility study report required for information technology projects, and to complete the contracting process for development and operation of the new data system.

3) Related Legislation. Assemblyman Paul Koretz has introduced AB 1437 which prohibits "inappropriate marketing" of prescription drugs. The bill incorporates existing guidelines on drug marketing adopted by the Pharmaceutical Research and Manufacturing Association and enacts fines to be issued by the Department of Health Services of up to $20,000 per violation for "inappropriate marketing." A copy of AB 1437 is attached for your reference.

4) History.

Mar. 26	Re-referred to Com. on B. & P.
Mar. 25	Read second time and amended.
Mar. 24	From committee: Amend, do pass as amended, and re-refer to Com. on B. & P. (Ayes 13. Noes 9.) (March 18).
Mar. 6	Re-referred to Com. on HEALTH.
Mar. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 27	Referred to Coms. on HEALTH and B. & P.
Jan. 13	From printer. May be heard in committee February 12. Read first time.
Jan. 10	Introduced. To print.

Board of Pharmacy
Draft Amendments to AB 103 (As Amended March 25, 2003)

SECTION 1. Section 4168 is added to the Business and Professions Code, to read:

4168. (a) ~~On or before January 1 of each year, a pharmaceutical~~ Each pharmaceutical manufacturing company shall disclose to the board the following information for each ~~recipient name and value, nature, and purpose of any~~ gift, fee, payment, subsidy, or other economic benefit it provided directly or through its pharmaceutical marketers ~~or wholesale distributors~~ in connection with detailing, promotional, or other marketing activities related to a dangerous drug or dangerous device to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs or dangerous devices in this state~~.~~:

(1) Name, address, category of licensure, and license number of the recipient.
(2) Value of the economic benefit provided.
(3) Description of the economic benefit provided.
(4) Name of the individual arranging for the provision of the economic benefit.
(5) Name of the person providing the economic benefit.
(6) Date on which the economic benefit was provided.

Disclosure shall be made ~~on a form and~~ in the time and ~~a~~ manner prescribed by the board. The board may not require reporting more than four times per calendar year. The initial disclosure shall be made on or before January 1, 2008 ~~2005~~, for the period beginning on July 1, 2006~~2003~~, and ending June 30, 2007~~2004~~.

(b) The board shall report to the Governor and the Legislature on or before March 1 of each year, commencing in 2008~~2005~~, the information disclosed to it pursuant to this section. The report shall include, but not be limited to, summary data regarding the number of marketing personnel in California, the dollar value of economic benefits provided to prescribers and dispensers, nature of the economic benefits to prescribers and dispensers, and geographic variation, if any, in the provision of economic benefits provided to prescribers and dispensers. The board shall publish the data reported pursuant to this section on its website.

~~(b)~~ (c) A pharmaceutical manufacturing company shall also disclose to the board, on or before October 1, 2007~~2004~~, and annually thereafter, the name and address of the individual responsible for the company's compliance with the provisions of this section.

~~(c) The board shall not disclose information identified as a trade secret by the pharmaceutical manufacturing company in its disclosure.~~

(d) The following shall be exempt from disclosure:

(1) A complimentary sample of a dangerous drug intended to be furnished to a patient.
(2) The payment of reasonable compensation and reimbursement of expenses in connection with a clinical trial.
(3) Any gift, fee, payment, subsidy, or other economic benefit having a value of less than twenty-five dollars ($25).

(e) A civil penalty or administrative fine in the amount of ten thousand dollars ($10,000) may be assessed for each violation of this section. Each failure to disclose constitutes a separate violation of this section for which the civil penalty or administrative fine may be assessed. The prevailing plaintiff in the action seeking a civil penalty shall be awarded costs and reasonable attorney's fees in addition to the civil penalty. If the board is the prevailing plaintiff, the civil penalty, costs, and attorney's fees shall be deposited into the Pharmacy Board Contingent Fund.

(f) The following definitions apply for purposes of this section:

(1) "Clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.

(2) "Pharmaceutical manufacturing company" means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly ~~,~~ or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Pharmaceutical manufacturing company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. "Pharmaceutical manufacturing company" shall not mean a pharmacy.

(3) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase a dangerous drug.

~~(4) "Dangerous drug" means any drug that is unsafe for self-use and includes any of the following:~~

~~(A) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.~~

~~(B) Any drug or device that, pursuant to federal or state law, may be dispensed only on prescription, or that is furnished pursuant to Section 4006. "Dangerous drug" does not include labeled veterinary drugs.~~

(g) The board shall implement this section to the extent funds are appropriated from the General Fund in the annual budget act or to the extent that funding is made available by a non-profit agency.

AMENDED IN ASSEMBLY MARCH 25, 2003

AMENDED IN ASSEMBLY MARCH 5, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 103

Introduced by Assembly Members Reyes and Koretz
(Coauthors: Assembly Members Hancock and Lieber)
(Coauthors: Senators Chesbro, Romero, and Soto)

January 10, 2003

An act to add Section 4168 to the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 103, as amended, Reyes. Pharmaceuticals: marketing activities.

Existing law, the Pharmacy Law, regulates wholesalers and manufacturers of dangerous drugs and makes the California State Board of Pharmacy responsible for administering and enforcing the provisions of that law. Under the Pharmacy Law, all revenue collected by the board is deposited into the Pharmacy Board Contingent Fund. The Pharmacy Law makes a violation of its provisions punishable as a crime.

This bill would require a pharmaceutical manufacturing company, as defined, to annually disclose to the board certain information regarding the economic benefits the company provides in connection with its marketing activities, including disclosing the names of the recipients of any benefits and the value, nature, and purpose of the benefits. The bill

would also require the board to report annually to the Governor and the Legislature regarding these disclosures.

The bill would impose a civil penalty of $10,000 for the violation of its disclosure requirements and would specify that awards obtained by the board be deposited into the Pharmacy Board Contingent Fund.

The bill, by specifying an additional requirement under the Pharmacy Law, the violation of which is ~~punishable as~~ a ~~criminal offense~~ *crime*, would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4168 is added to the Business and Professions Code, to read:

4168. (a) On or before January 1 of each year, a pharmaceutical manufacturing company shall disclose to the board the recipient name and value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit it provided directly or through its pharmaceutical marketers or wholesale distributors in connection with detailing, promotional, or other marketing activities to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state. Disclosure shall be made on a form and in a manner prescribed by the board. The initial disclosure shall be made on or before January 1, 2005, for the period beginning on July 1, 2003, and ending June 30, 2004. The board shall report to the Governor and the Legislature on or before March 1 of each year, commencing in ~~2006~~ *2005*, the information disclosed to it pursuant to this section.

(b) A pharmaceutical manufacturing company shall also disclose to the board, on or before October 1, 2004, and annually

thereafter, the name and address of the individual responsible for the company's compliance with the provisions of this section.

(c) The board shall not disclose information identified as a trade secret by the pharmaceutical ~~marketing~~ *manufacturing* company in its disclosure.

(d) The following shall be exempt from disclosure:

(1) A complimentary sample of a dangerous drug intended to be furnished to a patient.

(2) The payment of reasonable compensation and reimbursement of expenses in connection with a clinical trial.

(3) Any gift, fee, payment, subsidy, or other economic benefit having a value of less than twenty-five dollars ($25).

(e) A civil penalty in the amount of ten thousand dollars ($10,000) may be assessed for each violation of this section. Each failure to disclose constitutes a separate violation of this section for which the civil penalty may be assessed. The prevailing plaintiff in the action shall be awarded costs and reasonable attorney's fees in addition to the civil penalty. If the board is the prevailing plaintiff, the civil penalty, costs, and attorney's fees shall be deposited into the Pharmacy Board Contingent Fund.

(f) The following definitions apply for purposes of this section:

(1) ''Clinical trial'' means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.

(2) ''Pharmaceutical manufacturing company'' means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly~~,~~ or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. ''Pharmaceutical manufacturing company'' also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs.

(3) ''Pharmaceutical marketer'' means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state to a physician, hospital, nursing home, pharmacist, health

benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase a dangerous drug.

(4) "Dangerous drug" means any drug that is unsafe for self-use and includes any of the following:

(A) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(B) Any drug or device that, pursuant to federal or state law, may be dispensed only on prescription, or that is furnished pursuant to Section 4006.

"Dangerous drug" does not include labeled veterinary drugs.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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AMENDED IN ASSEMBLY APRIL 10, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 1437

Introduced by Assembly Member Koretz

February 21, 2003

An act to add Article 6 (commencing with Section 110424.8) to Chapter 4 of Part 5 of Division 104 of the Health and Safety Code, and to add Section 14105.37 to the Welfare and Institutions Code, relating to drug marketing practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 1437, as amended, Koretz. Drug marketing practices.

Existing law, the Sherman Food, Drug, and Cosmetic Law, contains various provisions regarding the packaging, labeling, and advertising of food, drugs, and cosmetics. A violation of any of these provisions is punishable as a misdemeanor*, and shall also subject the violator, upon conviction, to a fine in the amount of $1,000, or if the violation is committed after a previous conviction has become final, to a fine in the amount of $10,000*.

This bill would make it unlawful, under that law, for any person to engage in inappropriate marketing of any drug or device ~~used in the treatment of life-threatening chronic conditions~~ to physicians or other medical providers. *It would also provide, notwithstanding the above penalty provisions, that violations of this provision or related regulations shall subject the violator, upon conviction, to fines of up to $20,000 per violation, as specified.*

~~This bill would also require every pharmaceutical manufacturing company to disclose to the State Department of Health Services the~~

~~value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with certain drug marketing activities, with certain exceptions.~~

This bill would create a new crime, thereby imposing a state-mandated local program.

Existing law provides for the Medi-Cal program, administered by the State Department of Health Services, under which qualified low-income persons are provided with health care services, including prescription benefits. Under existing law, the department pays participating pharmacists a discounted price for drugs on a Medi-Cal list of contract drugs, and obtains best price rebates from drug manufacturers.

This bill would require the department, during each negotiation with a manufacturer regarding the purchase ~~price of a drug or~~ *of one or more* drugs *or devices* used to treat a life-threatening condition, *as defined,* to require the manufacturer to disclose the aggregate marketing costs for the ~~drug or~~ drugs *or devices* that are the subject to the negotiation.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Article 6 (commencing with Section 110424.8) is added to Chapter 4 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 6. Drug Marketing Practices

110424.8. (a) It is unlawful for any person to engage in inappropriate marketing of any drug or device ~~used in the treatment of life-threatening chronic conditions~~ to physicians or other medical providers.

(b) For purposes of this section, ‘‘inappropriate marketing’’ means any action intended to entice a physician or other medical

provider to employ a drug or device in the treatment of a patient by offering any of the following:

(1) Cash payments to physicians of any kind.

(2) Gifts to physicians that are not directly related to the benefit of the patient or the practice of the physician related to the drug or device.

(3) Travel, meals, or lodging for the physician unless they are associated with legitimate physician education.

(4) Any payment or subsidy for other cost that is not directly related to the benefit of the patient or the practice of the physician related to the drug or device.

~~(c) For purposes of this section, "life-threatening chronic condition" means a condition or disease that requires specialized medical care over a prolonged period of time and will result in death within five years without an appropriate drug regimen.~~

~~110424.85. (a) Every pharmaceutical manufacturing company shall disclose to the department, on a quarterly basis, the value, nature, and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing facility, pharmacist, health benefit plan administrator or any other person in California authorized to prescribe, dispense, or purchase prescription drugs in this state. Disclosure shall be made on a form and in a manner prescribed by the department.~~

~~(b) Each company subject to the requirements of subdivision (a) shall also disclose to the department annually the name and address of the individual responsible for compliance with that subdivision.~~

~~(c) The department shall keep confidential all trade secret information disclosed to the department pursuant to subdivision (a). The disclosure form prescribed by the department shall permit the company to identify any information that is a trade secret.~~

~~(d) The following shall be exempt from disclosure:~~

~~(1) Free samples of prescription drugs intended to be distributed to patients.~~

~~(2) The payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials. As used in this paragraph, "clinical trial" means an~~

~~approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.~~

~~(3) Any gift, fee, payment, subsidy, or other economic benefit the value of which is less than twenty-five dollars ($25).~~

~~(4) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policymaking conference of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.~~

~~(e) As used in this section:~~

~~(1) ''Pharmaceutical marketer'' means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in the state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.~~

~~(2) ''Pharmaceutical manufacturing company'' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a wholesale drug distributor or pharmacist.~~

(c) For purposes of receiving additional guidance regarding practices that constitute "inappropriate marketing," the department shall refer to the Compliance Program Guidance for Pharmaceutical Manufacturers, issued by the United States Department of Health and Human Services' Office of the Inspector General.

110424.85. Notwithstanding Section 111825, any person who violates this article or any regulation adopted pursuant to this

article shall, if convicted, be subject to a fine of not more than ten thousand dollars ($10,000) per violation. If the violation is committed after a previous conviction under this article that has become final, the person shall be subject to a fine of not more than twenty thousand dollars ($20,000) per violation. Every individual action that violates this article shall be considered a separate violation.

SEC. 2. Section 14105.37 is added to the Welfare and Institutions Code, to read:

14105.37. *(a) (1)* During each negotiation with a manufacturer regarding the purchase of ~~a drug or drugs~~ *one or more drugs or devices* that are used to treat a life-threatening condition, the department shall require the manufacturer to disclose the aggregate marketing costs for the ~~drug or drugs~~ *drugs or devices* that are the subject of that negotiation. The department shall keep this data confidential, although the department, on an annual basis and without identifying any manufacturer in any way, shall provide aggregate *industry-wide* marketing cost information *by therapeutic category* to the relevant committees in both houses of the Legislature and to the Legislative Analyst.

(2) The department shall, for purposes of this subdivision, determine what constitutes marketing costs.

(b) For purposes of this section, "life-threatening" means either of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes where the end point of clinical intervention is survival.

(c) Except as otherwise provided in subdivision (a), the data collected pursuant to this section shall not be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment C

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 261 **VERSION: AS AMENDED MARCH 19, 2003**

AUTHOR: MADDOX **SPONSOR: AUTHOR**

RECOMMENDED POSITION: SUPPORT

SUBJECT: BACKROOM CLINICS

Existing Law:

1) Prohibits the dispensing or furnishing of dangerous drugs or dangerous devices without a license. (Health & Safety Code 11352.1)

2) Imposes a misdemeanor penalty and/or $5,000 fine for the unlicensed dispensing or furnishing of dangerous drugs or dangerous devices. (Health & Safety Code 11352.1)

3) Permits local health officers to issue immediate cease and desist orders against those dispensing or furnishing dangerous drugs or dangerous devices without a license. (Health & Safety Code 101070)

This Bill:

1) Increases the penalty for unlicensed dispensing of dangerous drugs or dangerous devices to include the option of felony prosecution. (H&S 11352.1)

2) Provides that the provision relating to the closure of unlicensed pharmacies by local health officers shall not be construed as to diminish the authority of local law enforcement to enforce any criminal law relating to the unlawful dispensing or furnishing of a controlled substance, as specified. (H&S 101070)

3) Exempts the furnishing or dispensing of hypodermic needles or syringes. (H&S 11352.1)

Comment:

1) Author's Intent. According to the author, "Drug smugglers running black market pharmaceutical rings are taking advantage of recent immigrants looking to purchase the same medicines they used at home. These medicines are smuggled into California and often fail to meet the Federal Drug Administration's (FDA) quality control standards. They regularly lack warnings and proper dosage, and are frequently sold at exorbitant prices. The deaths of two toddlers have been linked to black market medicine rings. This bill will help rid the community of unlicensed doctors and pharmacists by increasing the penalty from a misdemeanor to an alternate felony/misdemeanor for the sale or distribution of illegal pharmaceutical medicines."

2) Wobbler. This bill establishes a "wobbler" penalty for the unlicensed distribution of dangerous drugs or dangerous devices. A wobbler gives prosecutors the option of charging the case as either a misdemeanor or a felony. Wobblers are created to address crimes that have the potential to vary substantially in the severity of the offense or to address individuals who are repeatedly prosecuted for the same offense. This wobbler provision was included in the legislation that originally established this offense, but the penalty was reduced to a misdemeanor in the Senate Public Safety Committee.

3) Prior Legislation. The board supported similar legislation (AB 394) which failed passage last year.

4) History.

Apr. 2	In committee: Placed on Appropriations suspense file.
Mar. 20	Re-referred to Com. on APPR.
Mar. 19	Read second time and amended.
Mar. 18	From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (March 11).
Feb. 11	Referred to Com. on PUB. S.
Feb. 02	From printer. May be heard in committee March 7.
Feb. 04	Read first time. To print.

5) Support & Opposition.

Support

California District Attorneys Association
Los Angeles County Sheriffs' Office
Orange County District Attorney's Office

Opposition

American Civil Liberties Union
California Attorneys for Criminal Justice
Drug Policy Alliance Network

AMENDED IN ASSEMBLY MARCH 19, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 261

Introduced by Assembly Member Maddox

February 4, 2003

An act to amend Sections 11352.1 and 101070 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 261, as amended, Maddox. Controlled substances: dispensing or furnishing without a license.

(1) Existing *law makes it a misdemeanor to possess a hypodermic needle or syringe except when acquired as provided by law, and existing law makes possession of a device used for unlawful injection of controlled substances a misdemeanor, as provided. Separately, existing* law provides that any person who knowingly and unlawfully dispenses or furnishes a dangerous drug or dangerous device, or who knowingly owns, manages, or operates a business that dispenses or furnishes a dangerous drug or dangerous device, without a license to dispense or furnish these products, is guilty of a misdemeanor, punishable as specified.

This bill would ~~instead~~ *exempt from this last provision a person who dispenses or furnishes a hypodermic syringe, needle, or similar device, and would* make a violation of ~~the above~~ *this* provision a misdemeanor or a felony. By providing for the prosecution of the offense as a felony with its attendant prosecutorial costs, this bill would impose a state-mandated local program.

(2) Existing law authorizes a local health officer who determines that a person within his or her jurisdiction is unlawfully dispensing or furnishing specified drugs requiring a prescription, a dangerous drug or device, or a controlled drug, to take specified action, including the immediate closure of a business upon a reasonable suspicion that the business poses an immediate threat to the public health, welfare, or safety, as defined.

This bill would declare that nothing in that provision shall be construed to diminish the authority of local law enforcement to enforce any criminal law relating to the unlawful dispensing or furnishing of controlled substances.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11352.1 of the Health and Safety Code is amended to read:

11352.1. (a) The Legislature hereby declares that the dispensing and furnishing of prescription drugs, controlled substances, and dangerous drugs or dangerous devices without a license poses a significant threat to the health, safety, and welfare of all persons residing in the state. It is the intent of the Legislature in enacting this provision to enhance the penalties attached to this illicit and dangerous conduct.

(b) Notwithstanding Section 4321 of the Business and Professions Code, and in addition to any other penalties provided by law, any person who knowingly and unlawfully dispenses or furnishes a dangerous drug or dangerous device, or any material represented as, or presented in lieu of, any dangerous drug or dangerous device, as defined in Section 4022 of the Business and Professions Code, or who knowingly owns, manages, or operates a business that dispenses or furnishes a dangerous drug or dangerous device or any material represented as, or presented in

lieu of, any dangerous drug or dangerous device, as defined in Section 4022 of the Business and Professions Code without a license to dispense or furnish these products, shall be guilty of a misdemeanor or a felony. Upon the first conviction, each violation shall be punishable by imprisonment in a county jail not to exceed one year or ~~by~~ imprisonment in the state prison, ~~or~~ by a fine not to exceed five thousand dollars ($5,000), or by both that fine and imprisonment. Upon a second or subsequent conviction, each violation shall be punishable by imprisonment in a county jail not to exceed one year or ~~by~~ imprisonment in the state prison, or ~~by~~ a fine not to exceed ten thousand dollars ($10,000), or by both that fine and imprisonment.

(c) Subdivision (b) shall not apply to any person who dispenses or furnishes an object described in paragraph (7) of subdivision (a) of Section 11014.5.

SEC. 2. Section 101070 of the Health and Safety Code is amended to read:

101070. (a) (1) The Legislature hereby finds and declares that the dispensing or furnishing of drugs requiring a prescription pursuant to Section 111470, a controlled substance as defined in Section 4021 of the Business and Professions Code, or a dangerous drug or a dangerous device as defined in Section 4022 of the Business and Professions Code, without a license poses a significant threat to the public health, safety, and welfare of all residents of the state. In recent years, the public has become increasingly exposed to a proliferation of persons who engage in these illegal or dangerous acts.

(2) The Legislature further finds and declares that extraordinary measures are needed to control this burgeoning problem. Therefore, the occasional enlistment of local health officers in regulatory and enforcement functions normally reserved to the state is appropriate and necessary in order to protect the health, safety, and welfare of all persons of this state.

(3) Notwithstanding the foregoing, nothing contained in this section shall be construed as limiting or supplanting the authority of the state agencies charged with the regulation of the practice of pharmacy.

(b) Whenever a local health officer determines that there exists in his or her jurisdiction any person who, without a license, is dispensing or furnishing drugs requiring a prescription pursuant to

Section 111470, a controlled substance as defined in Section 4021 of the Business and Professions Code, or a dangerous drug or a dangerous device as defined in Section 4022 of the Business and Professions Code, the local health officer may take action against that person. This action shall include, but not be limited to:

(1) Receiving and investigating complaints from the public, from other licensees or from health care facilities that a person is engaging in any or all of the activity set forth in this subdivision. In conducting any investigation pursuant to this paragraph, the local health officer shall have the assistance of, and be accompanied by, a licensed pharmacist. The local health officer shall provide the Board of Pharmacy, and any other state agency charged with jurisdiction over the activity set forth in this subdivision, with a copy of all complaints received pursuant to this paragraph.

(2) Issuing an order to the person to immediately cease and desist from the unlawful activity described in this subdivision, after confirming that the person is engaging in any or all of the activity set forth in this subdivision, and determining that the person has not been convicted of engaging in that activity pursuant to Section 11352.1 or any other applicable provision of law. In issuing the order, the local health officer shall notify the person that the activity is illegal in the State of California. In the event the local health officer determines that any or all of the items described in this subdivision must be confiscated, in addition to the cease and desist order, the local health officer shall enlist the aid of local law enforcement to execute confiscation of those items.

(3) Order the closure of the business, if any, operated, managed, or owned by the person after confirming that the person is engaging in any or all of the activity set forth in this subdivision, and determining whether the person has previously been convicted of engaging in that activity pursuant to Section 11352.1 or any other applicable provision of law. If the public health officer has a reasonable suspicion that the operation of a business poses an immediate threat to public health, welfare, or safety, the business may be ordered closed immediately while the hearing described in subdivision (c) is pending. Immediate danger to the public health, welfare, or safety includes, but is not limited to, evidence that the person is providing, selling, or distributing drugs that require a prescription, or dangerous drugs, devices, or controlled substances

without a license. In the event that the local health officer determines that any or all of the items described in this subdivision must be confiscated in addition to the closure of the business, that officer shall enlist the aid of local law enforcement to execute the confiscation of those items.

(c) (1) Any person engaging in any or all of the activity described in subdivision (b) whose business is closed as a result of action by *a* local health officer pursuant to subdivision (b) shall be entitled to a hearing to show cause why the closure was unwarranted.

(2) Whenever a local health officer orders the closure of a business pursuant to subdivision (b), the local health officer shall immediately issue to the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section, and informing the owner of the right to a hearing, if requested, to show cause why the business should not be closed.

(3) A written request for a hearing shall be submitted by the person to the local health officer within 15 calendar days of closure. A failure to request a hearing within 15 calendar days of closure shall be deemed a waiver of the right to a hearing.

(4) The hearing shall be held within 15 calendar days of the receipt of a request for a hearing; however, when circumstances warrant, the hearing officer may order a hearing at any reasonable time within this 15-day period to expedite the hearing process. Upon written request of the person, the hearing officer may postpone any hearing date, if circumstances warrant the postponement.

(5) The hearing officer shall issue a written notice of decision to the person within five working days following the hearing. In the event the hearing officer determines that the closure was warranted, the notice shall specify the acts or omissions with which the person is charged, and shall state that the business shall remain closed permanently. Evidence that the person engaged in any or all of the activity set forth in subdivision (b) shall constitute prima facie evidence that permanent closure is warranted. Any business still operating shall close immediately upon receipt of the written decision ordering closure.

(d) Nothing in this section shall be construed to diminish the authority of local law enforcement to enforce any criminal law

relating to the unlawful dispensing or furnishing of controlled substances, including, but not limited to, Section 11352.1.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment D

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 521 **VERSION: AS INTRODUCED**

AUTHOR: DIAZ **SPONSOR: CA CONGRESS OF SENIORS & SENIOR LEGISLATURE**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: DRUG INFORMATION

Existing Law:

1) Requires pharmacists to provide oral consultation to each patient with a new prescription or when deemed necessary in the pharmacist's professional judgment. (16CCR1707.2)

2) Requires pharmacists to inform the patient, either orally or in writing, of the harmful effects of a drug when those effects impairs the ability to drive a vehicle or when taken in conjunction with alcohol. (B&P 4074)

This Bill:

Requires pharmacists to provide a large-print informational insert for each prescription drug if the drug poses a substantial risk of harm if taken in combination with alcohol or other medications. (B&P 4074.5)

Comment:

1) Author's Intent. This bill is sponsored by the California Congress of Seniors and the California Senior Legislature. The bill has been introduced to reduce adverse medication interactions by providing patients with more information about their medications. The author notes that this problem is particularly significant in older populations who use more prescription drugs which increases the likelihood of interactions with other prescription drugs and over-the-counter drugs.

2) Drafting Concerns. The bill requires pharmacists to provide printed material informing patients about interactions with alcohol or other drugs (both over-the-counter and prescription drugs). Existing law (section 4074) requires pharmacists to inform patients (either verbally or in writing) of drug interactions with alcohol or that may impair the patient's ability to drive. This requirement should be modified to eliminate a reference to interactions with alcohol since the new section requires providing the written material specifically for alcohol interactions. Attached are proposed amendments that will address this duplication.

3) History.

Feb. 27	Referred to Com. on HEALTH.
Feb. 19	From printer. May be heard in committee March 21.
Feb. 18	Read first time. To print.

Board of Pharmacy
Draft Amendments to AB 521, As Introduced

Section 1. Amend Section 4074 of the Business and Professions Code, to read:

4074. (a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription ~~if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or~~ if the drug may impair a person' s ability to drive a motor vehicle~~, whichever is applicable~~, and provided the drug is determined by the board pursuant to subdivision (b) to be a drug or drug type for which this warning shall be given.
(b) The board may by regulation require additional information or labeling.
(c) This section shall not apply to drugs furnished to patients in conjunction with treatment or emergency services provided in health facilities or, except as provided in subdivision (d), to drugs furnished to patients pursuant to subdivision (a) of Section 4056.
(d) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each medication given at the time of discharge and each medication given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each medication, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other provision of law shall be construed to require that only a pharmacist provide this consultation.

4074.5. A pharmacist shall include ~~a large-print~~ an informational insert, printed in at least 12 point type, with each drug dispersed by prescription informing the patient when the drug poses a substantial risk of harm to the person consuming the drug if taken in combination with alcohol or other medications, including both prescription and nonprescription drugs. This section shall become operative on January 1, 2005.

ASSEMBLY BILL No. 521

Introduced by Assembly Member Diaz

February 18, 2003

An act to add Section 4074.5 to the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 521, as introduced, Diaz. Prescription drug warnings.

Existing law, the Pharmacy Law, requires a pharmacist to inform a patient, orally or in writing, of certain information about the harmful effects of a prescription drug taken in combination with alcohol. Existing law makes the violation of the Pharmacy Law a crime.

This bill would additionally require a pharmacist to include a large-print informational insert with each drug dispensed by prescription informing the patient when the drug poses a substantial risk of harm if taken in combination with alcohol or other medication.

Because a violation of this requirement would be punishable as a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4074.5 is added to the Business and Professions Code, to read:

4074.5. A pharmacist shall include a large-print informational insert with each drug dispersed by prescription informing the patient when the drug poses a substantial risk of harm to the person consuming the drug if taken in combination with alcohol or other medications, including both prescription and nonprescription drugs.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment E

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 746 **VERSION: AS AMENDED MARCH 28, 2003**

AUTHOR: MATTHEWS **SPONSOR: NONE**

RECOMMENDED POSITION: SUPPORT

SUBJECT: MEDI-CAL FRAUD

Existing Law:

1) Permits the board to revoke licenses. (B&P 4300)

2) Requires the board to take disciplinary action for unprofessional conduct. (B&P 4301)

3) Defines unprofessional conduct to include both:

- The commission of any act involving moral turpitude, dishonesty, **fraud**, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

- The cash settlement of a violation of the Medi-Cal program.

(B&P 4301)

This Bill:

Requires health professional licensing boards (including the Board of Pharmacy) to revoke a license if the licensee is convicted of more than one charge of Medi-Cal fraud. (B&P 490.7)

Comment:

1) Author's Intent. The author introduced this legislation to address the ongoing fraud problem in the Medi-Cal program. The board already prosecutes cases against pharmacists and pharmacies that engage in Medi-Cal fraud. The Pharmacy Law already defines any type of fraud as unprofessional conduct which may result in professional discipline.

2) History.

Apr. 8	In committee: Hearing postponed by committee.
Apr. 1	Re-referred to Com. on B. & P.
Mar. 28	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Mar. 3	Referred to Com. on B. & P.
Feb. 20	From printer. May be heard in committee March 22.
Feb. 19	Read first time. To print.

AMENDED IN ASSEMBLY MARCH 28, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 746

Introduced by Assembly Member Matthews

February 19, 2003

An act to add Section 490.7 to the Business and Professions Code, relating to the healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 746, as amended, Matthews. ~~Medical fraud~~ *Fraud: healing arts*: revocation of professional licenses.

Existing law establishes the ~~State~~ Department of Consumer Affairs, which is comprised of various boards, including, but not limited to, the Dental Board of California, the Medical Board of California, the State Board of Optometry, the California State Board of Pharmacy, and the Board of Psychology, among others, which each issue licenses.

Existing law authorizes a board to suspend or revoke a license if the licensee has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

Existing law provides for the Medi-Cal program, pursuant to which ~~medical~~ *health care* benefits are provided to public assistance recipients and certain other low-income persons, *including dental benefits under the Denti-Cal element of the Medi-Cal program.* Under existing law, the Director of Health Services is required to suspend the participation in the Medi-Cal program by a provider of services for conviction of any felony or any misdemeanor involving fraud~~, among other things~~.

This bill would require a board *within the department, the Osteopathic Medical Board of California, and the State Board of Chiropractic Examiners* to revoke a license if the licensee has more than one conviction for any felony or misdemeanor involving fraud committed by the licensee in his or her capacity as a provider of services under the Medi-Cal program *or the Denti-Cal element of the Medi-Cal program.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 490.7 is added to the Business and Professions Code, to read:

490.7. *(a)* A board shall revoke a license, pursuant to Section 490, if the licensee is licensed pursuant to Division 2 (commencing with Section 500) and has more than one conviction of any felony or misdemeanor involving fraud committed by the licensee in his or her capacity as a provider of services under the Medi-Cal program, *including the Denti-Cal element of the Medi-Cal program,* pursuant to Chapter 7 (commencing with Section 14000), or Chapter 8 (commencing with Section 14200), of Part 3 of Division 9 of the Welfare and Institutions Code.

(b) "Board," as used in this section, includes each board in Division 2 (commencing with Section 500) and also includes the Osteopathic Medical Board of California and the State Board of Chiropractic Examiners.

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Attachment F

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 1363 **VERSION: AS INTRODUCED**

AUTHOR: BERG **SPONSOR: COUNTY HEALTH OFFICERS ASSN**

RECOMMENDED POSITION: SUPPORT

SUBJECT: HYPODERMICS

Existing Law:

1) Specifies that public entities and their agents or employees shall not be subject to criminal prosecution for operating a needle exchange program authorized by a public entity pursuant to a declaration of a local health emergency. (H&S 11364.7)

2) Requires that hypodermic needles and syringes be sold only by a pharmacy, dentist, veterinarian, podiatrist or by the holder of a hypodermic needle and syringe license issued by the board. (B&P 4142)

3) Requires the distribution of hypodermic needles and syringes to be regulated by the Board of Pharmacy. (B&P 4140)

4) Requires a prescription to obtain a hypodermic needle or syringe. (B&P 4142)

5) Exempts hypodermic needles and syringes for the administration of insulin and adrenaline from the prescription requirement. (B&P 4145)

6) Exempts hypodermic needles and syringes for use in animals from the prescription requirement. (B&P 4145)

7) Exempts hypodermic needles and syringes for industrial use from the prescription requirement. (B&P 4144)

8) Defines hypodermic needles and syringes used with illicit drugs as drug paraphernalia. (H & S 11014.5)

9) Imposes misdemeanor penalties for the unlawful sale of drug paraphernalia. (H & S 11364.7)

This Bill:

1) Repeals the prescription requirement for hypodermic needles and syringes. (B&P 4145)

2) Permits needle exchange programs operated by local governments to furnish needles and syringes without a prescription and without a permit from the board. (B&P 4145)

3) Requires cities or counties operating needle exchange programs to do so only under the following circumstances:

a. Consultation with the state Department of Health Services.
b. Development of operating procedures by the local health officer for the exchange of hypodermic needles and syringes.
c. Development of a database relating to the exchange needles.
d. Provision of community outreach and preventive education to reduce exposure to HIV infection and blood-borne hepatitis.
e. Demonstrate effort to secure treatment for drug addiction for participants.
f. Involvement of the community in the development of the project.
g. Involvement of local public safety officials in the development of the project. (H&S 121346)

4) Requires assessment of exchange project results. (H&S 121346)

Comment:

1) Author's Intent. The author is seeking to increase the availability of clean needles and syringes to reduce the transmission of blood-borne diseases such as hepatitis and HIV. The bill accomplishes this by both removing the prescription requirement for needles and syringes and broadening the law permitting clean needle exchange programs operated by local governments.

2) Past Legislation. Assembly Bill 136 (Chapter 762, Statutes of 1999) removed potential criminal prosecution for clean needle exchange programs operated by public entities or the agents of public entities. Legislation in that same session that exempted needles distributed in a clean needle program operated by a public entity from the prescription requirement was rejected by the Governor.

3) Senate Bill 1785. In 2002, Senator John Vasconcellos introduced Senate Bill 1785 which eliminated the prescription requirement for needles and syringes and instead required that they only be sold by a pharmacist. The bill also limited the quantity sold to 30 needles per purchase. That bill was supported by the board and vetoed by the Governor. The veto message is provided below:

> To the Members of the California State Senate:
>
> I am returning Senate Bill 1785 without my signature.
>
> SB 1785 would authorize pharmacists and physicians to furnish hypodermic needles or syringes for human use without a prescription. In addition, persons who are 18 years of age or older would be able to possess up to 30 hypodermic needles or syringes.
>
> I am committed to the underlying goal of the bill which is to reduce the transmission of HIV and hepatitis C among injection drug users, and I am proud of the progress we have made in combating these two diseases. California spends $93.2 million on education and prevention programs and I have added millions of dollars in the Office of AIDS for behavioral and early intervention, programs for high-risk youth, communities of color and HIV prevention evaluation. I have strongly supported our new HIV reporting system which will reveal trends in HIV transmission and assist in targeting HIV education, prevention and care efforts. I have signed legislation that already makes hypodermic needles and syringes available from authorized, legally sanctioned syringe exchange programs located throughout California.
>
> In Spring 2000, the Department of Health Services appointed the Hepatitis C Working Group, comprised of key stakeholders from the public and private sectors. The Working Group

developed the first-ever hepatitis C strategic plan for California. In August 2000, I signed SB 1256 (Polanco) which allocated $1.5 million for hepatitis C outreach and education.

I worked hard with the author of the legislation I signed in 1999 to bring law enforcement and health officials together on a bill that would decriminalize supervised needle exchange programs. This bill undermines the key elements that won my support for that legislation:

* It eliminates the requirement for a one-for-one exchange of syringes, which is the standard of practice in authorized needle exchange programs.
* By eliminating the one-on-one exchange, this bill eliminates the ability to focus aggressive intervention efforts toward getting drug addicts into treatment.
* It eliminates the requirement that needle exchange programs be conducted with local government approval, ongoing oversight and as the result of a declared health emergency.

Additionally, this bill could potentially increase the amount of contaminated needles and syringes in parks, beaches and other public areas. This would place the non-injection drug using population at greater risk for HIV, hepatitis C, and other blood-borne diseases. While I appreciate the author's hard work and dedication to this issue, I cannot sign this measure.

The board supported SB 1785.

4) Related Legislation. Senate Bill 774 (Vasconcellos) has been introduced in this session that is substantially the same as Senate Bill 1785 referenced above.

5) History.

Mar. 6	Referred to Com. on HEALTH.
Feb. 24	Read first time.
Feb. 23	From printer. May be heard in committee March 25.
Feb. 21	Introduced. To print.

ASSEMBLY BILL No. 1363

Introduced by Assembly Member Berg

February 21, 2003

An act to repeal and add Section 4145 of the Business and Professions Code, and to add Chapter 16 (commencing with Section 121345) to Part 4 of Division 105 of the Health and Safety Code, relating to AIDS.

LEGISLATIVE COUNSEL'S DIGEST

AB 1363, as introduced, Berg. AIDS: clean needle and syringe exchange program.

Existing law authorizes pharmacists and physicians to furnish hypodermic needles and syringes without a prescription or permit for human use in the administration of insulin or adrenaline if certain conditions are met.

Existing law prohibits any public entity, and its agents or employees, from being subject to criminal prosecution for distribution of hypodermic needles or syringes to participants in clean needle and syringe exchange projects authorized by the public entity pursuant to a declaration of a local emergency due to the existence of a critical local public health crisis.

This bill would authorize cities, counties, or cities and counties to develop clean needle and syringe exchange projects that contain prescribed components, and would authorize pharmacists, physicians, and certain persons authorized under those projects to furnish hypodermic needles and syringes without a prescription or permit.

This bill would require that a participating county, city, or city and county assess the project using certain criteria, and submit a progress report that takes into consideration data from the assessment to the

Director of Health Services, the Governor, and the chairpersons of both health committees of the Legislature.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The rapidly spreading acquired immune deficiency syndrome (AIDS) epidemic, and the more recent spread of blood-borne hepatitis, pose an unprecedented public health crisis in California, and threaten, in one way or another, the life and health of every Californian.

(b) Injection drug users are the second largest group at risk of becoming infected with the human immunodeficiency virus (HIV) and developing AIDS, and they are the primary source of heterosexual, female, and perinatal transmission in California, the United States, and Europe.

(c) According to the Office of AIDS, injection drug use has emerged as one of the most prevalent risk factors for new AIDS cases in California.

(d) Studies indicate that the lack of sterile needles available on the streets, and the existence of laws restricting needle availability promote needle sharing, and consequently the spread of HIV among injection drug users. The sharing of contaminated needles is the primary means of HIV transmission within the injection drug user population.

(e) Most injection drug users use a variety of drugs, mainly heroin, cocaine, and amphetamines. Because amphetamine- and cocaine-injecting drug users inject more frequently than heroin users, their risk for HIV infection is higher.

SEC. 2. Section 4145 of the Business and Professions Code is repealed.

~~4145. Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use in the administration of insulin or adrenaline; a pharmacist or veterinarian may, without a prescription or license, furnish hypodermic needles and syringes for use on poultry or animals;~~

~~and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use in the administration of insulin or adrenaline, or from a pharmacist, veterinarian, or licenseholder, for use on poultry or animals; if all of the following requirements are met:~~

~~(a) No needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.~~

~~(b) The furnisher, at the time furnishing occurs, makes a record of the furnishing in the manner required by Section 4146.~~

SEC. 3. Section 4145 is added to the Business and Professions Code, to read:

4145. (a) Notwithstanding any other provision of law, the following persons may, without a prescription or permit, furnish a hypodermic needle or syringe if all the requirements in subdivision (c) are met:

(1) A pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use in the administration of insulin or adrenaline.

(2) A pharmacist or veterinarian may, without a prescription or permit, furnish hypodermic needles and syringes for use on poultry or animals.

(3) A pharmacist, physician, or other person designated under the operating procedures developed pursuant to paragraph (1) of subdivision (b) of Section 121346 of the Health and Safety Code may, without a prescription or permit, furnish hypodermic needles and syringes when operating a clean needle and syringe exchange project and any person may, without a prescription or a permit, obtain hypodermic needles and syringes from a program established pursuant to Chapter 16 (commencing with Section 121345) of Part 4 of Division 105 of the Health and Safety Code.

(b) Any person may, without a prescription or permit, obtain hypodermic needles and syringes from a pharmacist or physician for human use in the administration of insulin or adrenaline, or from a pharmacist, veterinarian, or permitholder for use on poultry or animals if all the requirements in subdivision (c) are met.

(c) (1) No needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

(2) The furnisher, at the time the furnishing occurs, shall make a record of the furnishing in the manner required by Section 4146.

SEC. 4. Chapter 16 (commencing with Section 121345) is added to Part 4 of Division 105 of the Health and Safety Code, to read:

CHAPTER 16. CLEAN NEEDLE AND SYRINGE EXCHANGE PROGRAM

121345. (a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to attempt to reduce the spread of HIV infection and blood-borne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange program pursuant to this chapter in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121346.

121346. (a) A city and county, or a county, or a city with or without a health department that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Health Services, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Secretary of Health and Human Services, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and blood-borne hepatitis infection among injection drug users. Providers and users of an exchange project authorized by the

county, city, or city and county shall not be subject to criminal prosecution for possession of syringes or needles during participation in an exchange project.

(b) Each project shall include, but not be limited to, all of the following:

(1) The development of a set of operating procedures by the local health officer for the furnishing and exchange of hypodermic needles and syringes for injection drug users and the approval of the operating procedures by the county, city, or city and county.

(2) The development of a data base and collection of data relating to the furnishing and replacement of clean hypodermic needles and syringes to injection drug users by persons designated in the operating procedures developed pursuant to paragraph (1). The data collected pursuant to this paragraph shall be reported to the department annually commencing two years after the inception of the project.

(3) The provision of community outreach and preventive education that is culturally sensitive and linguistically appropriate to reduce project participants' exposure to HIV infection and blood-borne hepatitis.

(4) A demonstrated effort to secure treatment for drug addiction for participants upon their request.

(5) The involvement of the community in the development of the project.

(6) The involvement of local public safety officials in the development of the project.

(7) Accessibility of the project to the target population while being sensitive to community concerns.

(8) Appropriate levels of staff expertise in working with injection drug users and adequate staff training in providing community referrals, needle hygiene, and safety precautions.

(9) Enhanced treatment capacity, insofar as possible, for injection drug users.

(10) Preferential acceptance, insofar as possible, of HIV-infected drug users into drug treatment programs.

(c) The projects authorized pursuant to this chapter shall be part of a network of voluntary and confidential HIV services, where available, including, but not limited to, all of the following:

(1) Anonymous HIV antibody testing and counseling.

(2) Hepatitis screening, counseling, and vaccination.

(3) Notwithstanding Section 121015, voluntary, anonymous, or confidential partner notification.

(4) Early intervention and ongoing primary medical care followup for infected persons and their partners.

(5) Social services to support families of HIV-infected drug users.

(d) Components of the projects authorized pursuant to this chapter shall be assessed as to their effectiveness by the participating city and county, county, or city. Assessment shall include, but not be limited to, the following measures, where they are available:

(1) The incidence of HIV among the subject population.

(2) Needle exchange rates.

(3) Level of drug use.

(4) Level of needle sharing.

(5) Use of condoms.

(6) Availability of needle exchange programs in the jurisdiction.

(7) Program participation rates.

(8) The number of participants referred for treatment.

(9) The status of treatment and recovery of those entering substance abuse treatment programs.

(10) Referrals for HIV, sexually transmitted diseases, and hepatitis screening and treatment.

(11) Referrals for, or provision of, primary medical care.

(e) All components of the projects authorized pursuant to this chapter shall be voluntary. Where persons are provided services as a part of a project, including, but not limited to, antibody testing, counseling, or medical or social services, those provisions of law governing the confidentiality and anonymity of that information shall apply. All information obtained in the course of implementing a project that personally identifies any person to whom needle furnishing and exchange services are provided shall remain confidential and shall not be released to any person or agency not participating in the project without the person's written consent.

(f) A city and county, county, or city with or without a health department initiating a clean needle and syringe exchange project, shall submit a progress report two years from the project's inception. The report shall take into consideration available data

on factors listed in subdivision (d). The report shall be submitted to the director, the Governor, and the chairpersons of both health committees of the Legislature.

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Attachment G

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 1460 **VERSION: AS AMENDED MARCH 28, 2003**

AUTHOR: NATION **SPONSOR: CPHA**

RECOMMENDED POSITION: SUPPORT

SUBJECT: LABORATORY DIRECTORS

Existing Law:

1) Permits a physician or a person licensed as a clinical laboratory director to act as a clinical laboratory director. (B&P 1209)

2) Requires clinical laboratory directors to meet the requirements established by the federal Clinical Laboratory Improvement Amendments (CLIA). (B&P 1209)

3) Requires the clinical laboratory director to be responsible for the operation of the clinical laboratory including:

- administration
- selecting and supervising laboratory procedures
- reporting laboratory test results
- ensuring compliance with CLIA
- supervising laboratory personnel

This Bill:

Permits pharmacists to act as a laboratory director when they receive training required of laboratory directors and the laboratory performs only waived tests . (B&P 4052.1)

Comment:

1) Author's Intent. The bill was introduced to permit pharmacists to perform waived tests in a pharmacy without an outside laboratory director. The sponsor indicates that amendments are forthcoming that reflect this intent. The sponsor further indicates, that by permitting pharmacists to perform waived tests in a pharmacy, patients will have better access to tests required to appropriately manage their drug therapy.

2) CLIA?. Prior to 1988, less that 10% of all clinical laboratories were required to meet quality standards. Approximately 12,000 hospitals and independent laboratories were regulated under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and the Medicare and Medicaid programs. Congressional hearings revealed serious deficiencies in quality in physician office laboratories and in Pap smear testing. Studies have demonstrated that laboratories meeting minimum personnel and quality requirements perform better than those that do not. CLIA '88 was passed to provide assurance to the public that access to safe, accurate laboratory testing is available. Currently, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all 150,000 clinical laboratories, including physician office laboratories, are regulated to ensure the quality of test results.

The CLIA '88 regulation unified and replaced past standards with the single set of requirements that apply to laboratory testing of human specimens. Standards for laboratory personnel, quality control and quality assurance are based on test complexity and potential harm to the patient.

3) Complexity. Determining which CLIA '88 standards apply to a test depends upon the level of complexity of that test. Three categories of testing complexity have been defined under CLIA '88. They are waived, moderate and high. One reason the tests are placed into categories is to reduce the burden of regulation for those laboratories performing tests for which a low probability of an erroneous result exists. For example, there are no personnel or inspection requirement for the waived category of testing. In addition, 75% of all tests falls within the moderate complexity category which permits an individual with only a high school degree and appropriate training to perform these tests.

4) California CLIA. CLIA permits a state with stricter clinical laboratory standards to obtain an exemption from federal regulation (and fees) if the lab tests and personnel that would be subject to CLIA are regulated by that state's clinical lab law.

Prior to the enactment of the CLIA, California already had an extensive administrative scheme for regulating clinical labs and lab personnel. However, that state law was not, in all respects, equal to or greater in regulatory oversight coverage to CLIA. Consequently, in 1995 the Legislature enacted SB 113 to bring California's clinical lab law into compliance with all of CLIA's requirements so that California could obtain a waiver from CLIA and continue to regulate its clinical labs at the state level.

One of the key components of CLIA and state clinical lab law was the requirement that clinical labs be overseen by a lab director who would be responsible for the quality control of the testing and the competency and training of the personnel who were conducting the tests. Besides a licensed physician, California law permits other persons, a licensed bioanalyst or a clinical chemist to qualify as a lab director.

5) History.

Apr. 8	In committee: Hearing postponed by committee.
Apr. 1	Re-referred to Com. on B. & P.
Mar. 28	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Mar. 13	Referred to Coms. on B. & P. and HEALTH
Feb. 24	Read first time.
Feb. 23	From printer. May be heard in committee March 25.
Feb. 21	Introduced. To print.

AMENDED IN ASSEMBLY MARCH 28, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 1460

Introduced by Assembly Member Nation

February 21, 2003

An act to amend ~~Sections 1209 and~~ *Section* 4052.1 of the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 1460, as amended, Nation. Clinical laboratory directors.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists. Under that law, a pharmacist is authorized to perform routine patient assessment procedures that are defined, in part, by reference to regulations adopted by a federal agency. Existing law also provides for the regulation of clinical laboratories and specifies the qualifications required to serve as a laboratory director. Under existing law, the violation of these provisions is punishable as a crime.

This bill would reflect the change of name of the federal agency that adopted those particular regulations. The bill would also authorize a pharmacist to be a laboratory director of a clinical laboratory that provides routine patient assessment procedures under designated conditions. Because the bill would specify these conditions, the violation of which would be punishable as a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

~~SECTION 1. Section 1209 of the Business and Professions Code is amended to read:~~

~~1209. (a) (1) As used in this chapter, ''laboratory director'' means any person who is a duly licensed physician and surgeon, or is licensed to direct a clinical laboratory under this chapter and who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory. The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.~~

~~(2) A pharmacist may be a laboratory director of a clinical laboratory that provides routine patient assessment procedures if the clinical laboratory has received a certificate of waiver under CLIA and the regulations adopted pursuant to it by the federal Centers for Medicare and Medicaid Services, and the pharmacist has completed a training program on the duties and responsibilities of a laboratory director.~~

~~(b) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to assure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and~~

~~report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.~~

~~(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.~~

~~(c) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.~~

~~(d) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:~~

~~(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.~~

~~(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and~~

~~proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.~~

~~(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.~~

~~(c) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.~~

~~(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:~~

~~(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.~~

~~(B) Monitoring the recording and reporting of test results.~~

~~(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.~~

~~(D) Direct observation of performance of instrument maintenance and function checks.~~

~~(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.~~

~~(F) Assessment of problem solving skills.~~

~~(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.~~

~~(f) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:~~

~~(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high quality service.~~

~~(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.~~

~~As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.~~

~~(g) Subdivision (f) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.~~

~~SEC. 2.~~

SECTION 1. Section 4052.1 of the Business and Professions Code is amended to read:

4052.1. (a) Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, ‘‘routine patient assessment procedures’’ means either of the following:

(1) Procedures that a patient could, with or without a prescription, perform for himself or herself.

(2) Clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Centers for Medicare and Medicaid Services, as authorized by paragraph (11) of subdivision (a) of Section 1206.5.

~~(b)~~ A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician

designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(b) A pharmacist may serve as a laboratory director under Section 1209 in a clinical laboratory that provides routine patient assessment procedures if the clinical laboratory where the tests are performed has received a certificate of waiver under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted pursuant to it by the federal Centers for Medicare and Medicaid Services, and the pharmacist has completed a training program on the duties and responsibilities of a laboratory director consistent with the requirements of Section 1209.

~~SEC. 3.~~

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment H

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 151 **VERSION: AS AMENDED APRIL 8, 2003**

AUTHOR: BURTON **SPONSOR: CMA, AM CANCER SOCIETY, COMPASSION IN DYING**

RECOMMENDED POSITION: SUPPORT

SUBJECT: TRIPLICATE PRESCRIPTIONS

Existing Law:

1) Establishes the Controlled Substance Review and Evaluation System (CURES) as a pilot project to electronically monitor the dispensing of Schedule II controlled substances in outpatient pharmacies. (H&S 11165)

2) Requires pharmacies to electronically report dispensing data on all Schedule II prescriptions to the Department of Justice on a monthly basis. (California Code of Regulations, Title 16, Section 1715.5)

3) Sunsets the CURES pilot project on January 1, 2008. (H&S 11165)

4) Requires that prescriptions for Schedule II controlled substances to be written on three-part (triplicate) forms issued by the Department of Justice. (H&S 11164)

5) Permits prescribers to use ordinary prescription forms for Schedule II controlled substance if the patient has a terminal illness. (H&S 11159.2)

This Bill:

1) Repeals the triplicate requirement for Schedule II controlled substances.

2) Makes the CURES program permanent.

3) Requires all controlled substance prescriptions be written on forgery resistant paper on and after July 1, 2004.

Comment:

1) Author's Intent. Medical research has consistently documented that prescription pads issued by law enforcement deters physician prescribing for pain due to physician fears about law enforcement oversight. California has an electronic monitoring system for Schedule II prescriptions that provides a more effective monitoring system than the carbon copy system adopted in the 1940s.

Pain is an issue that everyone understands and wishes to avoid. According to proponents, patients in California experiencing severe pain have a 50-50 chance of

having their pain treated appropriately. One of the major reasons for this unfortunate fact is that the State of California is one of only three states in the nation that require a special, serialized prescription pad issued by the State Department of Justice in order for physicians to prescribe Schedule II drugs.

2) Prior Legislation. In 2000, the board sponsored AB 2018 (Thomson) which proposed to repeal the triplicate and make CURES permanent. AB 2018 was defeated in that form, but ultimately passed and was signed by Governor Davis in an alternate form that reduced the administrative hassles associated with the triplicate prescriptions. In 2001, Senator Johannessen introduced SB 1000 to make CURES permanent and repeal the triplicate in an early form. The bill was ultimately amended to state legislative intent to repeal the triplicate and to make further administrative changes to the CURES program. This bill was supported by the board and vetoed by the Governor. In 2002, the board sponsored AB 2655 (Matthews) to extend the CURES program and to allow practitioners to access patient information in the CURES system. That bill was signed by the Governor and took effect on January 1, 2003.

3) Board Policy. The board has had a long standing policy of supporting the treatment of pain and supportive of repealing the triplicate requirement in California. The board spearheaded the development of CURES as an electronic replacement for the triplicate monitoring system. The board provided start up funding for CURES and funding for the first 5 years of operation through a $1.3 million appropriation from the Pharmacy Board Contingent Fund.

4) Amendments. The bill was amended on April 8, 2003 to sketch out an agreement reached between the sponsors of the bill and the law enforcement community. This agreement repeals the triplicate and replaces it with a privately printed, forgery resistant prescription pad required for all controlled substance prescriptions. The parties will be negotiating the text of this proposal in coming weeks.

5) History.

Apr. 8	Read second time. Amended. Re-referred to Com. on PUB. S.
Apr. 7	From committee: Do pass as amended, but first amend, and re-refer to Com. on PUB. S. (Ayes 9. Noes 0. Page 395.)
Mar. 10	Set for hearing March 26.
Feb. 25	To Coms. on H. & H.S. and PUB. S.
Feb. 11	From print. May be acted upon on or after March 12.
Feb. 7	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 8, 2003

SENATE BILL No. 151

Introduced by Senator Burton
(Coauthors: Senators Aanestad, Kuehl, and Torlakson)
(Coauthors: Assembly Members Berg, Canciamilla, Cohn, Dymally, Leno, and Lowenthal)

February 7, 2003

An act to amend *Section 11165 of, and to amend, repeal, and add* Sections 11164, ~~11165,~~ 11165.1, ~~11167, and 11167.5~~ *and 11167* of, and to *amend and* repeal Sections 11161, 11162.5, *11167.5,* and 11169 of, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 151, as amended, Burton. Controlled substances: Schedule II.

Existing law provides that no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense such a prescription unless it complies with specified requirements, one of which is that prescriptions for Schedule II controlled substances shall be prepared in triplicate. Existing law also provides for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program, as specified. The CURES program is scheduled to become inoperative on July 1, 2008, and repealed on January 1, 2009. *Existing law provides that a violation of any of these provisions is generally a misdemeanor.*

This bill would*, on and after July 1, 2004,* eliminate the triplicate prescription requirement for Schedule II controlled substances~~. The bill would~~*,* require prescribers of Schedule II controlled substances to meet the same prescription requirements imposed with respect to other

prescribable controlled substances*, and require prescriptions for any controlled substance to be issued on a secure forgery-resistant prescription paper. The prescription paper and vendor producing that paper would have to meet specified criteria established by the appropriate state board*. The bill would also provide for the indefinite continuation of the CURES program by deleting its repeal date. The bill would make conforming changes to related provisions. *By creating new crimes the bill would impose a state-mandated local program upon local government.*

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~no~~ *yes*.

The people of the State of California do enact as follows:

~~SECTION 1. Section 11161 of the Health and Safety Code is repealed.~~

~~SEC. 2. Section 11162.5 of the Health and Safety Code is repealed.~~

~~SEC. 3. Section 11164 of the Health and Safety Code is amended to read:~~

~~11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance unless it complies with the requirements of this section.~~

~~(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be subject to the following requirements:~~

~~(1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. With respect to prescriptions for controlled substances classified in Schedules II, III and IV, the signature, date, and information required by this~~

~~paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.~~

~~(2) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber. The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand. Notwithstanding any provision in this section, the prescriber's address, telephone number, category of professional licensure, or federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.~~

~~(3) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.~~

~~(b) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be reduced to writing by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription. The pharmacist need not reduce to writing the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient if that information is readily retrievable in the pharmacy. Pursuant to authorization of the prescriber, any employee of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the employee of the prescriber transmitting the prescription.~~

~~(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.~~

~~(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V~~

~~may be for more than one person in the same family with the same medical need.~~

~~SEC. 4.~~

SECTION 1. It is the intent of the Legislature in enacting this act that the requirement of Chapter 4 (commencing with Section 11150) of Division 10 of the Health and Safety Code that prescriptions for controlled substances classified in Schedule II shall be prepared in triplicate shall, on and after July 1, 2004, be replaced by the requirement that prescriptions for controlled substances classified in Schedule II, III, IV, and V shall be prepared on secure forgery resistant prescription paper.

SEC. 2. Section 11161 of the Health and Safety Code is amended to read:

11161. (a) Prescription blanks shall be issued by the Department of Justice in serially numbered groups of not more than 100 forms each in triplicate unless a practitioner orally, electronically, or in writing requests a larger amount, and shall be furnished to any practitioner authorized to write a prescription for controlled substances classified in Schedule II. The Department of Justice may charge a fee for the prescription blanks sufficient to reimburse the department for the actual costs associated with the preparation, processing, and filing of any forms issued pursuant to this section. The prescription blanks shall not be transferable. Any person possessing a triplicate prescription blank otherwise than as provided in this section is guilty of a misdemeanor.

(b) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all triplicate prescription blanks in the practitioner's possession at a time set in the order and shall direct the Department of Justice to withhold prescription blanks from the practitioner. The law enforcement agency obtaining the order shall notify the Department of Justice of this order. Except as provided in subdivisions (c) and (f) of this section, the order shall remain in effect until further order of the court. Any

practitioner possessing prescription blanks in violation of the order is guilty of a misdemeanor.

(c) The order provided by subdivision (b) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(d) The defendant may elect to challenge the order issued under subdivision (b) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (c) and any other evidence otherwise admissible at the preliminary examination.

(e) If the practitioner has not moved to vacate the order issued under subdivision (b) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (b) shall be vacated.

(f) Notwithstanding subdivision (e), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (b).

(g) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 3. Section 11162.5 of the Health and Safety Code is amended to read:

11162.5. (a) Every person who counterfeits a prescription blank purporting to be an official prescription blank prepared and issued pursuant to Section 11161, or knowingly possesses more than three such counterfeited prescription blanks, shall be punished by imprisonment in the state prison or by imprisonment in the county jail for not more than one year.

(b) Every person who knowingly possesses three or fewer counterfeited prescription blanks purporting to be official prescription blanks prepared and issued pursuant to Section 11161, shall be guilty of a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding one thousand dollars ($1,000), or by both.

(c) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 4. Section 11164 of the Health and Safety Code is amended to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance unless it complies with the requirements of this section.

(a) The signature on each prescription for a controlled substance classified in Schedule II shall be wholly written in ink or indelible pencil in the handwriting of the prescriber upon the official prescription form issued by the Department of Justice. Each prescription shall be prepared in triplicate, signed by the prescriber, and shall contain, either typewritten or handwritten by the prescriber or his or her employee, the date, name, and address of the person for whom the controlled substance is prescribed, the name, quantity, and strength of the controlled substance prescribed, directions for use, and the address, category of professional licensure, and the federal controlled substance registration number of the prescriber. The original and duplicate of the prescription shall be delivered to the pharmacist filling the prescription. The duplicate shall be retained by the pharmacist and the original, properly endorsed by the pharmacist with the name and address of the pharmacy, the pharmacy's state license number, the date the prescription was filled and the signature of the pharmacist, shall be transmitted to the Department of Justice at the

end of the month in which the prescription was filled. Upon receipt of an incompletely prepared official prescription form of the Department of Justice, the pharmacist may enter on the face of the prescription the address of the patient. A pharmacist may fill a prescription for a controlled substance classified in Schedule II containing an error or errors, if the pharmacist notifies the prescriber of the error or errors and the prescriber approves any correction. The prescriber shall fax or mail a corrected prescription to the pharmacist within seven days of the prescription being dispensed.

(b) Each prescription for a controlled substance classified in Schedule III, IV, or V, except as authorized by subdivision (c), shall be subject to the following requirements:

(1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. With respect to prescriptions for controlled substances classified in Schedules III and IV, the signature, date, and information required by this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber. The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand. Notwithstanding any provision in this section, the prescriber's address, telephone number, category of professional licensure, or federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.

(3) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(c) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted

prescription, which shall be reduced to writing by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. The date of issue of the prescription and all the information required for a written prescription by subdivision (b) shall be included in the written record of the prescription. The pharmacist need not reduce to writing the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient if that information is readily retrievable in the pharmacy. Pursuant to authorization of the prescriber, any employee of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the employee of the prescriber transmitting the prescription.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Notwithstanding any provision of subdivisions (b) and (c), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(f) In addition to the prescriber's record required by Section 11190, any practitioner dispensing a controlled substance classified in Schedule II in accordance with subdivision (b) of Section 11158 shall prepare a written record thereof on the official forms issued by the Department of Justice, pursuant to Section 11161, and shall transmit the original to the Department of Justice in accordance with any rules that the department may adopt for completion and transmittal of the forms.

(g) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 5. Section 11164 is added to the Health and Safety Code, to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V shall be written on a secure forgery resistant prescription paper.

(b) Both the prescription paper and the vendor producing that paper shall meet specified criteria established by the appropriate state board.

(c) This section shall become operative on July 1, 2004.

SEC. 6. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. CURES shall be implemented as a pilot project, commencing on July 1, 1997, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies between the two systems.

(b) The CURES pilot project shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision, shall not be disclosed, sold, or transferred to any third party.

~~SEC. 5. Section 11165.1 of the Health and Safety Code is amended to read:~~

~~11165.1. (a) (1) A licensed health care practitioner authorized to write a prescription for controlled substances classified in Schedule II or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.~~

~~(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.~~

~~(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.~~

~~(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.~~

~~SEC. 6. Section 11167 of the Health and Safety Code is amended to read:~~

~~11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a Schedule II controlled substance may be dispensed on an oral, written, or electronic data transmission order, subject to all of the following requirements:~~

~~(a) The order contains all information required by subdivision (a) of Section 11164.~~

~~(b) Any written order is signed and dated by the prescriber in indelible pencil or ink, and the pharmacy reduces any oral or electronic data transmission order to writing prior to actually dispensing the controlled substance.~~

~~SEC. 7. Section 11167.5 of the Health and Safety Code is amended to read:~~

~~11167.5. (a) An order for a controlled substance classified in Schedule II in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care may be dispensed upon an oral or electronically transmitted prescription. Prior to filling the prescription, the pharmacist shall reduce it to writing in ink or indelible pencil in the handwriting of the pharmacist upon an official prescription form issued by the Department of Justice for that purpose. The prescriptions shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed facility or home health agency providing hospice care in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, and federal controlled substance registration number of the prescriber. The prescription shall be properly endorsed by the pharmacist with the pharmacy's state license number, the signature of the pharmacist, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed facility or home health agency providing hospice care and shall be forwarded by the pharmacist to the Department of Justice at the end of the month in which the prescription was filled. A skilled nursing facility, intermediate care facility, or licensed home health agency providing hospice care shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.~~

~~(b) For the purposes of this section, ''hospice care'' means interdisciplinary health care which is designed to alleviate the physical, emotional, social, and spiritual discomforts of an individual who is experiencing the last phases of a terminal disease and to provide supportive care for the primary care person and the family of the patient under hospice care.~~

~~SEC. 8. Section 11169 of the Health and Safety Code is repealed.~~

SEC. 7. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to obtain triplicate prescription forms pursuant to Section 11161

or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(d) This section shall become inoperative on July 1, ~~2008~~ *2004*, and, as of January 1, ~~2009~~ *2005*, is repealed~~, unless a later enacted statute that is enacted before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed~~.

SEC. 8. Section 11165.1 is added to the Health and Safety Code, to read:

11165.1. (a) (1) A licensed health care practitioner authorized to write a prescription for controlled substances classified in Schedule II or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II controlled substances, the Department of Justice may initiate the referral of the history of controlled substances

dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(d) This section shall become operative on July 1, 2004, and shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute that is enacted before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 9. Section 11167 of the Health and Safety Code is amended to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a Schedule II controlled substance may be dispensed on an oral, written, or electronic data transmission order, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in indelible pencil or ink, and the pharmacy reduces any oral or electronic data transmission order to writing prior to actually dispensing the controlled substance.

(c) The prescriber provides a triplicate prescription, completed as provided by subdivision (a) of Section 11164, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a written, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 10. Section 11167 is added to the Health and Safety Code, to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a Schedule II controlled substance may be dispensed on an oral, written, or electronic data transmission order, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in indelible pencil or ink, and the pharmacy reduces any oral or electronic data transmission order to writing prior to actually dispensing the controlled substance.

(c) This section shall become operative on July 1, 2004.

SEC. 11. Section 11167.5 of the Health and Safety Code is amended to read:

11167.5. (a) An order for a controlled substance classified in Schedule II in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care may be dispensed upon an oral or electronically transmitted prescription. Prior to filling the prescription, the pharmacist shall reduce it to writing in ink or indelible pencil in the handwriting of the pharmacist upon an official prescription form issued by the Department of Justice for that purpose. The prescriptions shall be prepared in triplicate and shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed facility or home health agency providing hospice care in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, and federal controlled substance registration number of the prescriber. The duplicate shall be retained by the pharmacist, and the triplicate shall be forwarded to the prescriber by the end of the month in which the prescription was issued. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the signature of the pharmacist, the name and

address of the pharmacy, and the signature of the person who received the controlled substances for the licensed facility or home health agency providing hospice care and shall be forwarded by the pharmacist to the Department of Justice at the end of the month in which the prescription was filled. A skilled nursing facility, intermediate care facility, or licensed home health agency providing hospice care shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

(b) For the purposes of this section, ''hospice care'' means interdisciplinary health care which is designed to alleviate the physical, emotional, social, and spiritual discomforts of an individual who is experiencing the last phases of a terminal disease and to provide supportive care for the primary care person and the family of the patient under hospice care.

(c) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 12. Section 11169 of the Health and Safety Code is amended to read:

11169. *(a)* When codeine, or dihydrocodeinone or tincture opii camphorata (paregoric) is not combined with other medicinal ingredients, it shall be prescribed on the official triplicate blanks.

(b) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 13. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment I

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 175 **VERSION: AS INTRODUCED**

AUTHOR: KUEHL **SPONSOR: CAL. VET MED ASSN**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: VETERINARY DRUGS

Existing Law:

1) Defines "dangerous drugs" as those drugs for human use that require a prescription. (B&P 4022)

2) Excludes veterinary drugs from the definition of "dangerous drugs."

3) Excludes veterinarians from pharmacy law provisions relating to prescriber dispensing. (B&P 4170)

This Bill:

1) Redefines "dangerous drugs" to include veterinary drugs. (B&P 4022)

2) Includes veterinarians in existing prescriber dispensing statutes. (B&P 4170 et seq.)

Comment:

1) Author's Intent. The author introduced the bill to clarify existing law as it relates to the regulation of veterinary drugs by the Board of Pharmacy.

2) Veterinary Drugs. The Food and Drug Administration (FDA) approves drugs for veterinary use separately from those for human use. These drugs are approved for use in animals only upon a veterinarian's prescription. These drugs are excluded from the definition of "dangerous drugs" in Business and Professions Section 4022. The board is required to regulate dangerous drugs as defined in Section 4022 and cannot regulate a drug that does not meet the definition.

There are also a range of veterinary drugs approved for over-the-counter (OTC) sales that are chemically identical to human drugs available only by prescription. These drugs are commonly sold in pet and feed stores. The board is prohibited from regulating OTC drugs by Business and Professions Code Section 4057.

However, many drugs used in animals are drugs approved by the FDA for human use. These drugs (e.g., antibiotics, analgesics, etc) are dosed for animals but are the same drugs used to treat humans. These drugs are within the board's jurisdiction because they meet the definition of dangerous drugs in Section 4022.

As drafted, SB 175 would broaden the board's regulatory authority to include veterinary drugs and would subject veterinarians to board enforcement action. Existing law and

board practice is to share jurisdiction over prescriber dispensing cases with the appropriate licensing board. The board is presently engaged in a discussion regarding the enforcement of prescriber dispensing laws with the Medical Board of California.

3) Statutory History. In 1980 the section of law defining "dangerous drugs" (now Section 4022) was completely rewritten. Prior to that change, the section listed specific drugs that were dangerous drugs and exempted certain veterinary drugs from that definition. However, the 1980 revisions established a blanket exemption for all veterinary drugs. This change was characterized at the time as a technical change to streamline the law and follow federally established drug designations in place of the specific listing in current law.

Existing law identifies veterinarians as prescribers (B&P 4024), but veterinarians are exempted from the statutes regulating prescriber dispensing (B&P 4170 et seq.) that establish the rules for prescribers who dispense drugs directly to their own patients. Among the requirements under the prescriber dispensing statutes is that prescribers must allow the patient to fill the prescription at a pharmacy of their choosing. That requirement does not currently apply to veterinarians.

4) Amendments. Board staff has been engaged in discussions with the Veterinary Medical Board on this issue in recent months. Attached are amendments to the bill proposed by staff. These amendments address several technical drafting issues and clarify the meaning of "good faith medical examination" in the board's citation and fine authority relating to internet dispensing to include the definition of that phrase adopted by the Veterinary Medical Board.

5) History.

Apr. 10	In Assembly. Read first time. Held at Desk.
Apr. 10	Read third time. Passed. (Ayes 38. Noes 2.) To Assembly.
Apr. 8	Read second time. To third reading.
Apr. 7	From committee: Do pass. (Ayes 10. Noes 0. Page 471.)
Mar. 27	Set for hearing April 7.
Mar. 26	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 7. Noes 0. Page 361.) Re-referred to Com. on APPR.
Mar. 13	Set for hearing March 24.
Feb. 25	To Com. on B. & P.
Feb. 13	From print. May be acted upon on or after March 15.
Feb. 12	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Board of Pharmacy
Proposed Amendments to SB 175 (Kuehl)
As Introduced

SECTION 1. Section 4022 of the Business and Professions Code is amended to read:

4022. "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

SEC. 2. Section 4067 of the Business and Professions Code is amended to read:

4067. (a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal , or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars ($25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars ($25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

(f) For the purposes of this section “good faith prior examination” includes both the requirement for a physician and surgeon under Section 2242 of the Business and Professions Code and the requirement for a veterinary medical doctor under Title 16, Section 2032.1 of the California Code of Regulations.

SEC. 3. Section 4170 of the Business and Professions Code is amended to read:

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the State Board of Optometry, the Dental Board of California, the Veterinary Medical Board, or the Board of Osteopathic Examiners of this state.

SEC. 4. Section 4171 of the Business and Professions Code is amended to read:

4171. (a) Section 4170 shall not prohibit the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, no charge is made to the patient therefor, and an appropriate record is entered in the patient's chart.

(b) Section 4170 shall not apply to clinics, as defined in subdivision (a) of Section 1204 or subdivision (b) or (c) of Section 1206 of the Health and Safety Code, ~~to veterinarians furnishing drugs for the treatment of animals,~~ to programs licensed pursuant to Sections 11876, 11877, and 11877.5 of the Health and Safety Code, or to a prescriber dispensing parenteral chemotherapeutic agents, biologicals, or delivery systems used in the treatment of cancer.

SEC. 5 ~~4.~~ Section 4175 of the Business and Professions Code is amended to read:

4175. (a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, Veterinary Medical Board, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, or physician assistants

pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

SENATE BILL No. 175

Introduced by Senator Kuehl

February 12, 2003

An act to amend Sections 4022, 4067, 4170, and 4175 of the Business and Professions, relating to veterinary drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 175, as introduced, Kuehl. Veterinary drugs: prescriptions by veterinarians.

(1) Existing law, the Pharmacy Law, defines a dangerous drug but excludes properly labeled veterinary drugs from the definition.

This bill would modify this definition to delete the exception for veterinary drugs.

(2) Existing law authorizes specified licensed individuals to prescribe dangerous drugs and authorizes each licensing entity to enforce the provisions of the Pharmacy Law regarding the prescription of dangerous drugs.

This bill would authorize a licensed veterinarian to prescribe a dangerous drug and would authorize the Veterinary Medical Board to enforce the provisions of the Pharmacy Law regarding the prescription of dangerous drugs.

(3) Existing law requires the California State Board of Pharmacy to notify the appropriate licensing entity if the board receives a complaint relating to dangerous drugs dispensed by a prescriber.

This bill would require the board to notify the Veterinary Medical Board if it receives a complaint relating to dangerous drugs dispensed by a veterinarian.

(4) Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law.

Because violations of this bill would be a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4022 of the Business and Professions Code is amended to read:

4022. ''Dangerous drug'' or ''dangerous device'' means any drug or device unsafe for self-use ~~except veterinary drugs that are labeled as such,~~ *in humans or animals,* and includes the following:

(a) Any drug that bears the legend: ''Caution: federal law prohibits dispensing without prescription,'' ''Rx only,'' or words of similar import.

(b) Any device that bears the statement: ''Caution: federal law restricts this device to sale by or on the order of a ____,'' ''Rx only,'' or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

SEC. 2. Section 4067 of the Business and Professions Code is amended to read:

4067. (a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination *of a human or animal for whom the prescription is meant* if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination *of a human or animal,*

or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars ($25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars ($25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

SEC. 3. Section 4170 of the Business and Professions Code is amended to read:

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber’s own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the

recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, *the Veterinary Medical Board,* and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) ''Prescriber,'' as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, *a license to practice veterinary medicine,* or a certificate to practice podiatry, and who is duly registered ~~as such~~ by the Medical Board of California, the State Board of Optometry, the Dental Board of California, *the Veterinary Medical Board,* or the Board of Osteopathic Examiners of this state.

SEC. 4. Section 4175 of the Business and Professions Code is amended to read:

4175. (a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, *the Veterinary Medical Board*, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment J

SENATE BILL No. 361

Introduced by Senator Figueroa

February 19, 2003

An act to amend Sections 4001 and 4003 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 361, as introduced, Figueroa. Pharmacy: California State Board of Pharmacy.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy within the Department of Consumer Affairs. Under existing law, the board is authorized to appoint an executive director to exercise the powers and perform the duties delegated by the board. The law makes these provisions inoperative on July 1, 2004, and repeals them on January 1, 2005.

This bill would delete these inoperative and repeal dates and would extend the operation of these provisions to an unspecified date.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 11 members.

(b) The Governor shall appoint seven competent pharmacists~~,~~ ~~residing~~ *who reside* in different parts of the state~~,~~ to serve as

members of the board. The Governor shall appoint two public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, a community pharmacy, and a long-term health care or skilled nursing facility.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, ~~2004~~ ____, and, as of January 1, ~~2005~~ ____, is repealed, unless a later enacted statute, that becomes effective on or before January 1, ~~2005~~ ____, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 2. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, ~~2004~~ ____, and, as of January 1, ~~2005~~ ____, is repealed, unless a later enacted statute, that becomes effective on or before January 1, ~~2005~~ ____, deletes or extends the dates on which it becomes inoperative and is repealed.

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Attachment K

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 393 **VERSION: AS INTRODUCED**

AUTHOR: AANESTEAD **SPONSOR: CSHP**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in a field of study directly related to the duties of a pharmacy technician.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.
d. Has 1500 hours of experience as a pharmacy clerk.

This Bill:

1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. (B&P 4128)

2) Requires hospitals implementing TCT to do the following:

a. conduct ongoing training for technicians specified by the board in regulations.
b. conduct continuous quality improvement programs to audit the performance of technicians in TCT programs.
c. remove any technician in TCT programs whose accuracy rate falls below 99.9 percent.
d. possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO).
e. be inspected by the Board of Pharmacy.

f. establish a program using pharmacists to provide clinical services.
(B&P 4128)

3) Permits the board to adopt other rules related to TCT. (B&P 4128)

4) Requires the board to adopt rules specifying the criteria for TCT training programs. (B&P 4128)

5) Permits the board to order a hospital to cease a TCT program. (B&P 4128)

6) Requires that data and records for TCT programs be retained for three years. (B&P 4128)

7) Specifies that legal responsibility for errors in the TCT process is that of the pharmacy and the pharmacist-in-charge. (B&P 4128)

8) Requires hospitals to have a list of technicians in TCT programs available for inspection by the board. (B&P 4128.1)

9) Requires pharmacy technicians participating in TCT programs by certified by the Pharmacy Technician Certification Board. (B&P 4128.1)

Comment:

1) Author's Intent. The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy (attached) and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

2) Board History. At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

3) Regulations. The bill requires the board to adopt regulations specifying the criteria for TCT training programs. Such a requirement would both add workload for the board and delay implementation of TCT for at least one year due to the timeframes required in the rulemaking process. Placing these criteria in statute using the training programs developed by Cedars-Sinai and Long Beach Memorial as a guide would both save board resources and speed implementation of TCT.

Suggested Amendment #1 - The bill should be amended to remove the requirement for the board to adopt these criteria by regulation and the criteria should be added to the bill.

4) Records. The bill requires that TCT data and records be retained in the hospital for at least three years.

Suggested Amendment #3 – The bill should be amended to require that the records are readily retrievable by the pharmacy. This is the same standard applied to other pharmacy records.

5) History.

Apr. 8	Set for hearing April 28.
Mar. 6	To Com. on B. & P.
Feb. 21	From print. May be acted upon on or after March 23.

Feb. 20 Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 393

Introduced by Senator Aanestad

February 20, 2003

An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

SB 393, as introduced, Aanestad. Pharmacists: in-patient pharmacy technician services.

Existing law, the Pharmacy Law, authorizes the California State Board of Pharmacy to regulate, license, register, and discipline pharmacists and pharmacy technicians. Existing law authorizes a pharmacy technician working in an inpatient hospital or a correctional facility to perform nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist.

This bill would authorize a general acute care hospital to implement and operate a program using specially trained pharmacy technicians to check the work of other pharmacy technicians who have filled floor and ward stock and unit dose distribution systems for patients whose pharmacy prescriptions have been previously reviewed by a licensed pharmacist. The bill would require a hospital that operates this program to keep a list of all qualified pharmacy technicians available for board inspection and to keep all required data in the hospital for at least 3 years.

Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law. Because violations of this bill would be a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares that:

(a) Pharmacists have emerged as critical members of a medical team by providing services such as patient education, drug therapy monitoring, and pharmacokinetic consultations. Pharmacists often work side by side with physicians and nurses, and participate in medical rounds. Pharmacists play an integral role in ensuring a safe medication use process. Through interpretation, evaluation, and clarification of orders, pharmacists ensure the absence of drug allergies, interactions, duplications, and the optimal selection of dose, dosage form, frequency, route, and duration of therapy.

(b) There currently exists a shortage of pharmacists in the State, and this shortage has the potential to cause harm to patients because hospitals lack sufficient staffing to fully take advantage of clinical pharmacy programs that have been shown to reduce the number of medication errors in hospitals and improve patient outcomes.

(c) Studies authorized by the California State Board of Pharmacy, and conducted under the direction of the University of California, San Francisco, at major California hospitals, have established that certain non-discretionary functions currently performed by pharmacists in the hospital setting can safely be performed by properly trained pharmacy technicians. Specifically, allowing properly trained pharmacy technicians to check certain tasks performed by other pharmacy technicians is a safe and efficient use of staff, and frees pharmacists to provide the more important and skilled clinical pharmacy services that are critical to quality patient care and the reduction of medication errors.

(d) Pharmacists are substantially over-qualified for performing these non-discretionary in-patient checking functions, and current rules that require pharmacists to perform these functions

unnecessarily limit hospitals in their capacity to fully provide patients with clinical pharmacy services.

(e) It is the intent of the Legislature in enacting this act that pharmacists remain responsible for pharmacy operations. Nothing in these provisions should be interpreted to eliminate or minimize the role of pharmacists in directly supervising pharmacy technicians and pharmacy operations. It is the further intent of the Legislature that hospitals take advantage of the efficiencies created by these provisions by using properly trained pharmacy technicians for certain non-discretionary checking functions and more completely utilize the training and skills of their pharmacist staff to implement and expand clinical pharmacy programs at their facilities.

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. In-Patient Pharmacy Technician Services

4128. (a) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. The hospital may implement and operate this type of a program if all of the following requirements are met:

(1) The hospital conducts an ongoing training program pursuant to criteria the board, by regulation, has adopted for training pharmacy technicians. This criteria shall include both didactic and practical elements. Prior to adopting these regulations, the board shall approve a hospital's request to implement a pharmacy technician program if it is satisfied that the hospital has an adequate training program and meets the other requirements of this section.

(2) The hospital conducts a continuous quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months

for the first year, and annually thereafter. A pharmacy technician whose audited accuracy rate falls below 99.8 percent shall not be permitted to check the work of other pharmacy technicians until he or she is re-qualified pursuant to paragraph (1).

(3) The hospital has a current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.

(4) The hospital pharmacy has been inspected by the board.

(5) The hospital establishes and maintains a program utilizing pharmacists to provide clinical services as described in Section 4052.

(b) The board may, by regulation, establish other rules for hospitals utilizing specially trained pharmacy technicians pursuant to this section. The board shall adopt regulations establishing the criteria described in paragraph (1) of subdivision (a).

(c) The board may order a hospital to cease activities authorized by this section at any time a hospital fails to satisfy the board that it is capable of continuing to meet the requirements of this section.

(d) Data and records required by this section shall be retained in each participating hospital for at least three years.

(e) Medication that has been placed in floor or ward stock or unit dose distribution systems pursuant to this section shall not be administered to a patient except by a licensed health care provider practicing within the scope of his or her license.

(f) Legal responsibility or liability for errors or omissions that occur as a result of a pharmacy technician checking another pharmacy technician's work pursuant to this section shall be limited to the holder of the pharmacy permit and the pharmacist-in-charge.

4128.1. (a) Every hospital utilizing pharmacy technicians to check the work of other pharmacy technicians pursuant to Section 4128 shall maintain for inspection by the board a current list of all pharmacy technicians that have been qualified to perform checking functions.

(b) A pharmacy technician is not eligible to be qualified pursuant to this article unless he or she:

(1) Is currently certified by the Pharmacy Technician Certifying Board.

(2) Is currently registered with the board as a pharmacy technician pursuant to Section 4202.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment L

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 545

VERSION: AS INTRODUCED

AUTHOR: SPEIER

SPONSOR: AM. COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

SUBJECT: EMERGENCY CONTRACEPTION

Existing Law:

1) Permits pharmacists to dispense emergency contraception without a prescription if a protocol is established with a prescriber. (B&P 4052)

2) Requires that pharmacists complete a training program in emergency contraception before dispensing emergency contraception without a prescription. (B&P 4052)

3) Requires pharmacists dispensing emergency contraception without a prescription to furnish the patient with a standard fact sheet on emergency contraception developed by the board. (B&P 4052)

This Bill:

1) States legislative intent that women not be discriminated against when receiving emergency contraception and should not be treated differently than other classes of patients receiving services in a pharmacy.

2) Eliminates the requirement that pharmacists receive additional training before dispensing emergency contraception without a prescription. (B&P 4052)

3) Prohibits pharmacists from charging a separate consultation fee for dispensing emergency contraception that exceeds the dispensing fee charged for Medi-Cal. (B&P 4052)

4) Clarifies existing law to indicate that dispensing emergency contraception without a prescription does not require consultation above the general consultation required under board regulations. (B&P 4052)

5) Clarifies existing law to indicate that dispensing emergency contraception without a prescription does not require record keeping in excess of those required by existing board regulations. (B&P 4052)

6) Requires pharmacies participating in the Medi-Cal program to offer emergency contraception. (B&P 4427)

Comment:

1) Author's Intent. The author introduced this bill to assure the broadest possible access to emergency contraception. The sponsor believes that the charging of additional "consultation" fees to emergency contraception patients poses a barrier to access to emergency contraception for those patients who do not have a drug benefit covering emergency contraception. The sponsor characterizes this practice as discriminatory and contends that emergency contraception therapy does not require a consultation beyond that required for any new prescription.

2) Emergency Contraception. Emergency contraception (EC) drug therapy, commonly referred to as the "morning after pill" are hormone pills that when taken within 72 hours of unprotected intercourse, reduce the chance of a woman becoming pregnant by about 75 percent. The hormones are regular birth control pills containing estrogen and progestin, taken in two doses. In California and Washington, there is also available an EC pill known as "Plan B" made from synthetic progestin. The EC pills provide a short, high burst of hormone exposure that disrupts the hormone patterns essential for pregnancy. The EC pills reduce the hormone release from the ovary and the development of the uterine lining is disturbed, the disruptions are temporary, however, lasting only a few days. Depending on the time during the menstrual cycle when the EC pills are taken, they prevent pregnancy by inhibiting or delaying ovulation, or altering the lining of the uterus thereby inhibiting implantation of a fertilized egg. The EC pills can also prevent sperm from fertilizing an egg. EC pills do not cause an abortion. Because implantation occurs five to seven days after fertilization, EC pills work before implantation and not after a woman is already pregnant.

3) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation.

4) Related Legislation. Senator Dede Alpert introduced Senate Bill 490 in the current legislative session which permits pharmacists to dispense emergency contraception without a prescription according to a protocol approved by the board.

5) History.

Apr. 10	Withdrawn from committee. Re-referred to Com. on APPR.
Apr. 9	Withdrawn from committee. Re-referred to Com. on RLS.
Apr. 7	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 4. Noes 1. Page 471.) Re-referred to Com. on APPR.
Mar. 28	Set for hearing April 7.
Mar. 13	To Coms. on B. & P. and RLS.
Feb. 21	From print. May be acted upon on or after March 23.
Feb. 20	Introduced. Read first time. To Com. on RLS. for assignment. To print.

6) Support & Opposition

Support

The American College of Obstetricians and Gynecologists
(Sponsor)
California Catholic Conference
California Commission on the Status of Women
California Medical Association
California National Organization for Women
California Nurses Association
Planned Parenthood Affiliates of California

Opposition

California Pharmacists Association
California Society of Health-System Pharmacists

SENATE BILL No. 545

Introduced by Senator Speier

February 20, 2003

An act to amend Section 4052 of, and to add Section 4427 to, the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

SB 545, as introduced, Speier. Emergency contraception drug therapy.

Existing Law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy. Existing law requires a pharmacist to provide consultation when furnishing drugs, with certain exceptions, and the board has set forth specific requirements applicable to the provision of consultation and the maintenance of patient medication records. Existing law authorizes a pharmacist, in addition to other functions, to initiate emergency contraception drug therapy if the pharmacist has completed a training program on emergency contraception and certain other conditions are met.

This bill would remove this training requirement. The bill would also state that the provisions authorizing the initiation of emergency contraception drug therapy do not impose a duty on a pharmacist to provide consultation different from or to maintain patient medication records that differ from that which is generally required by the board's regulations. The bill would, however, require a pharmacist to ask questions necessary to determine a patient's eligibility for the therapy. The bill would also prohibit a pharmacist from charging a separate consultation fee for the initiation of emergency contraception drug therapy.

Existing law provides for the Medi-Cal program, administered by the State Department of Health Services, under which qualified low-income persons are provided with health care services, including prescription benefits. Under existing law, the department pays participating pharmacists a discounted price for drugs on the Medi-Cal drug formulary.

This bill would require a pharmacy that participates in the Medi-Cal program to offer the initiation of emergency contraception drug therapy. The bill would prohibit a pharmacist initiating emergency contraception drug therapy from charging a dispensing fee in excess of the dispensing fee charged to Medi-Cal patients.

Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law. All other violations of that law are infractions unless otherwise indicated.

Because this bill would create new prohibitions on pharmacists, the violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature to ensure equality of access to pharmaceuticals for the women of California. In ensuring that access, the Legislature intends to eliminate discriminatory practices relating to emergency contraception, which treat women differently from other classes of patients who receive their prescriptions through pharmacies.

SEC. 2. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the

patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice. ~~Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception, which includes, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation.~~ *A pharmacist may not charge a separate consultation fee to a patient for emergency contraception drug therapy that is initiated pursuant to this section, and may not charge a dispensing fee that is in excess of the dispensing fee charged to Medi-Cal patients for the initiation of emergency contraception drug therapy pursuant to this section.*

This paragraph does not impose a duty on a pharmacist to do any of the following:

(A) Provide a consultation different from that required pursuant to Section 1707.2 of Title 16 of the California Code of Regulations, except that a pharmacist shall ask questions necessary to determine patient eligibility for the initiation of emergency contraception drug therapy.

(B) Maintain patient medication records that differ from the requirements specified in Section 1707.1 of Title 16 of the California Code of Regulations.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using

the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 3. Section 4427 is added to the Business and Professions Code, to read:

4427. As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy shall offer as a service the initiation of emergency contraception drug therapy.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment M

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 774 **VERSION: AS INTRODUCED**

AUTHOR: VASCONCELLOS **SPONSOR: AUTHOR**

RECOMMENDED POSITION: SUPPORT

SUBJECT: HYPODERMIC NEEDLES

Existing Law:

1) Requires the distribution of hypodermic needles and syringes to be regulated by the Board of Pharmacy. (B&P 4140)

2) Requires a prescription to obtain a hypodermic needle or syringe. (B&P 4142)

3) Exempts hypodermic needles and syringes for the administration of insulin and adrenaline from the prescription requirement. (B&P 4145)

4) Exempts hypodermic needles and syringes for use in animals from the prescription requirement. (B&P 4145)

5) Exempts hypodermic needles and syringes for industrial use from the prescription requirement. (B&P 4144)

6) Defines hypodermic needles and syringes used with illicit drugs as drug paraphernalia. (Health & Safety Code 11014.5)

7) Imposes misdemeanor penalties for the unlawful sale of drug paraphernalia. (Health & Safety Code 11364.7)

This Bill:

1) Repeals the requirement for a prescription to purchase hypodermic needles and syringes at retail. (B&P 4142)

2) Permits individuals who are 18 years of age or older to purchase up to 30 hypodermic needles and syringes in a single transaction. (B&P 4142)

3) Requires pharmacies that sell hypodermic needles to restrict access to the needles to pharmacy personnel only. (B&P 4142)

4) Requires pharmacies that sell needles to provide purchasers with information regarding the safe disposal of the needles and penalties for disposing of them on a playground or school grounds. (B&P 4142.4)

5) Requires pharmacies selling needles to provide purchasers with information regarding drug addiction, availability of addiction treatment programs, and a telephone number to call for assistance and information regarding blood borne diseases. (B&P 4142.4)

6) Requires pharmacies selling needles to provide onsite needle disposal programs. (B&P 4142.6)

7) Repeals the requirement for sellers of needles to maintain a record of needle sales. (B&P 4146)

8) Requires pharmacies selling needles to report the number of needles sold per month and the number of transactions involving needles to the local public health officer monthly. (B& 4142.2)

9) Prohibits the disposal of needles at a playground or on school grounds subject to a fine up to $2,000 or imprisonment for up to 6 months. (B&P 4147)

10) Exempts possession of up to 30 needles from drug paraphernalia crimes. (H&S 11364)

11) Requires local public health officers to be available to pharmacies to consult regarding policies for sale of needles, review consumer education and treatment materials provided by pharmacies, needle disposal policies, and coordinate needle sales by pharmacies with existing local treatment programs. (B&P 4142)

Comment:

1) Author's Intent. The author seeks to increase access to hypodermic needles and syringes. The author points out numerous studies establishing the link between HIV transmission and intravenous drug use. These same studies indicate that the use of sterile syringes greatly reduces the transmission of HIV and other diseases among intravenous drug users. A bulletin supported by the U.S. Department of Health and Human Services called for the use of a new, sterile syringe for each injection by drug users. A coalition of health organizations including the American Medical Association, National Association of Boards of Pharmacy, and the American Pharmaceutical Association recommends that states take action to make clean needles and syringes available to intravenous drug users.

2) Previous Legislation. Assembly Bill 136 (Chapter 762, Statutes of 1999) removed potential criminal prosecution for clean needle exchange programs operated by public entities or the agents of public entities. Legislation in that same session that exempted needles distributed in a clean needle program operated by a public entity from the prescription requirement was rejected by the Governor.

Assembly Bill 1292 of 2001 proposed repealing the regulation of needles by the board. That bill was amended to a form substantially similar to this legislation. The bill was supported by the board subject to inclusion of amendments to resolve technical issues and repealing the requirement to issue a hypodermic permit. The bill was not taken to a hearing at the request of the author.

In 2002, Senator John Vasconcellos introduced Senate Bill 1785 which eliminated the prescription requirement for needles and syringes and instead required that they only be sold by a pharmacist. The bill also limited the quantity sold to 30 needles per purchase. That bill was supported by the board and vetoed by the Governor. The veto message is provided below:

> To the Members of the California State Senate:
>
> I am returning Senate Bill 1785 without my signature.

SB 1785 would authorize pharmacists and physicians to furnish hypodermic needles or syringes for human use without a prescription. In addition, persons who are 18 years of age or older would be able to possess up to 30 hypodermic needles or syringes.

I am committed to the underlying goal of the bill which is to reduce the transmission of HIV and hepatitis C among injection drug users, and I am proud of the progress we have made in combating these two diseases. California spends $93.2 million on education and prevention programs and I have added millions of dollars in the Office of AIDS for behavioral and early intervention, programs for high-risk youth, communities of color and HIV prevention evaluation. I have strongly supported our new HIV reporting system which will reveal trends in HIV transmission and assist in targeting HIV education, prevention and care efforts. I have signed legislation that already makes hypodermic needles and syringes available from authorized, legally sanctioned syringe exchange programs located throughout California.

In Spring 2000, the Department of Health Services appointed the Hepatitis C Working Group, comprised of key stakeholders from the public and private sectors. The Working Group developed the first-ever hepatitis C strategic plan for California. In August 2000, I signed SB 1256 (Polanco) which allocated $1.5 million for hepatitis C outreach and education.

I worked hard with the author of the legislation I signed in 1999 to bring law enforcement and health officials together on a bill that would decriminalize supervised needle exchange programs. This bill undermines the key elements that won my support for that legislation:

* It eliminates the requirement for a one-for-one exchange of syringes, which is the standard of practice in authorized needle exchange programs.
* By eliminating the one-on-one exchange, this bill eliminates the ability to focus aggressive intervention efforts toward getting drug addicts into treatment.
* It eliminates the requirement that needle exchange programs be conducted with local government approval, ongoing oversight and as the result of a declared health emergency.

Additionally, this bill could potentially increase the amount of contaminated needles and syringes in parks, beaches and other public areas. This would place the non-injection drug using population at greater risk for HIV, hepatitis C, and other blood-borne diseases. While I appreciate the author's hard work and dedication to this issue, I cannot sign this measure.

The board supported SB 1785.

3) Related Legislation. Assembly Bill 1363 (Berg) also repeals the prescription requirement and establishes more detailed authority for government operated needle exchange programs.

4) Hypodermic Permits. Currently any entity furnishing needles at retail must have either a pharmacy or hypodermic permit from the board. This bill would alter that and require all needles furnished for human use to be distributed by a pharmacy. Hypodermic permits would still be required to furnish needles for animal use (existing law exempts needles furnished for industrial use and this bill retains that exemption).

5) History

Mar. 25	Set for hearing April 23.
Mar. 13	To Coms. on H. & H.S. and RLS.
Feb. 24	Read first time.
Feb. 22	From print. May be acted upon on or after March 24.
Feb. 21	Introduced. To Com. on RLS. for assignment. To print.

SENATE BILL No. 774

Introduced by Senator Vasconcellos

February 21, 2003

An act to amend Sections 4140, 4142, 4145, and 4147 of, to add Sections 4142.2, 4142.4, 4142.6, and 4142.8 to, and to repeal Section 4146 of, the Business and Professions Code, and to amend Sections 11364 and 11364.5 of the Health and Safety Code, relating to hypodermic needles and syringes.

LEGISLATIVE COUNSEL'S DIGEST

SB 774, as introduced, Vasconcellos. Hypodermic needles and syringes.

(1) Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes. Under existing law, a prescription is required to purchase a hypodermic needle or syringe for human use, except to administer adrenaline or insulin.

This bill would authorize a licensed pharmacist to sell hypodermic needles or syringes to a person without a prescription under specified conditions.

(2) Existing law requires a person to properly establish his or her identity in order to purchase a needle or syringe. Existing law requires a pharmacist to keep detailed records of nonprescription sales of hypodermic needles and syringes.

This bill would delete both the identity requirement and the requirement that a pharmacist keep detailed records of nonprescription sales of hypodermic needles and syringes.

(3) Existing law prohibits the possession and sale of drug paraphernalia.

This bill would authorize a person to possess up to 30 hypodermic needles or syringes if acquired through an authorized source.

(4) Existing law prohibits the disposal of hypodermic needles and syringes in certain cases.

This bill would increase the criminal penalty for improper disposal of hypodermic needles and syringes in certain cases, thereby imposing a state-mandated local program.

(5) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Injection drug use is linked to 19 percent of all AIDS cases and one-half of all hepatitis C cases in California. Injection drug users become infected and transmit diseases such as HIV and hepatitis C to others by sharing blood-contaminated syringes.

(b) The lifetime cost of treating one person with AIDS is estimated to be over one hundred ninety-five thousand dollars ($195,000).

(c) According to the California Department of Health Services, 500,000 to 600,000 Californians are estimated to have contracted hepatitis C, a disease for which there is no known cure.

(d) The United States Public Health Service and the Centers for Disease Control and Prevention recommend that injection drug users who cannot or will not stop injecting drugs use a sterile needle for every injection as a public health measure to limit blood-borne disease transmission.

(e) Current California law requiring a prescription for the purchase of syringes and restricting the possession of syringes presents a formidable obstacle to disease prevention and threatens public safety. California is only one of six states that requires a prescription to purchase a syringe.

(f) Legislation to permit the pharmacy-based sale of sterile syringes without a prescription would reduce new cases of HIV,

hepatitis C, and other blood-borne diseases and would ultimately save California millions of dollars in medical costs.

SEC. 2. This act shall be known and may be cited as the Syringe Pharmacy Sale and Disease Prevention Act.

SEC. 3. Section 4140 of the Business and Professions Code is amended to read:

4140. ~~No~~ *A* person ~~shall~~ *may not* possess or have under his or her control ~~any~~ *a* hypodermic needle or syringe except when acquired in accordance with this article.

SEC. 4. Section 4142 of the Business and Professions Code is amended to read:

4142. *(a)* Except as otherwise provided by this article, ~~no~~ *a* hypodermic needle or syringe *for human use* shall *not* be sold at retail ~~except upon the prescription of a physician, dentist, veterinarian, or podiatrist.~~ *unless it is sold in a licensed pharmacy by either a pharmacist or a person licensed by the board to sell or furnish hypodermic needles or syringes.*

(b) A person who is 18 years of age or older may purchase for personal use pursuant to subdivision (a) up to 30 hypodermic needles or syringes per transaction without a prescription.

SEC. 5. Section 4142.2 is added to the Business and Professions Code, to read:

4142.2. A licensed pharmacy that sells nonprescription hypodermic needles and syringes at retail for human use shall do the following:

(a) Notify the local health officer, as defined in Chapter 1 (commencing with Section 101000) of Part 3 of Division 101 of the Health and Safety Code, that the pharmacy will be selling hypodermic needles and syringes without prescriptions.

(b) Store hypodermic needles and syringes so that they are available only to authorized personnel, and not openly available to customers.

(c) Report the number of syringes sold per month and the number of sales transactions for syringes and needles sold without a prescription per month to the local health officer.

SEC. 6. Section 4142.4 is added to the Business and Professions Code, to read:

4142.4. At the time of each purchase of nonprescription hypodermic needles and syringes at retail for human use, a

licensed pharmacy that sells those items shall provide a purchaser the following information:

(a) Information regarding the safe disposal of hypodermic needles and syringes that includes a notice of the penalties provided in Section 4147 for the improper disposal of hypodermic needles and syringes on playgrounds, public beaches, public parks, or school grounds.

(b) Public health information about the prevention, testing, and treatment of substance abuse, including a telephone number to call for assistance, and information on the transmission of blood-borne diseases, including information about the prevention, testing, and treatment of HIV and hepatitis C.

SEC. 7. Section 4142.6 is added to the Business and Professions Code, to read:

4142.6. A licensed pharmacy that sells nonprescription hypodermic needles and syringes at retail for human use shall provide one or more of the following safe syringe disposal programs:

(a) An onsite safe syringe disposal program.

(b) Make available for purchase mail-back sharps disposal packages that include postage paid, return packaging that is authorized by the United States Postal Service, a sharps container that meets applicable state and federal requirements, and tracking forms to verify destruction at a certified disposal facility.

(c) Make available for purchase or furnish personal sharps disposal containers and refer purchasers of nonprescription hypodermic needles and syringes to locally authorized, home-generated sharps consolidation points as defined in Section 117904 of the Health and Safety Code or to locally registered medical waste generators that accept home-generated medical sharps waste for disposal pursuant to Section 118147 of the Health and Safety Code.

SEC. 8. Section 4142.8 is added to the Business and Professions Code, to read:

4142.8. In order to maximize the public health benefits and public acceptance of the provisions of this article, the local health officer shall be available to do all of the following:

(a) Consult with pharmacies in establishing policies to sell hypodermic needles and syringes without a prescription.

(b) Review the appropriateness of information a licensed pharmacy is required to provide under Section 4142.4.

(c) Advise pharmacies, as necessary, on the options available within their jurisdiction for the disposal of used hypodermic needles and syringes that have been sold pursuant to this article.

(d) To the extent feasible, assist in coordinating activities authorized or required by this section with existing local programs directed at HIV, hepatitis C, and substance abuse treatment and prevention.

SEC. 9. Section 4145 of the Business and Professions Code is amended to read:

4145. Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use ~~in the administration of insulin or adrenaline~~; a pharmacist or veterinarian may, without a prescription or license, furnish hypodermic needles and syringes for use on poultry or animals; and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use ~~in the administration of insulin or adrenaline~~, or from a pharmacist, veterinarian, or licenseholder, for use on poultry or animals~~; if all of the following requirements are met:~~

~~(a) No needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.~~

~~(b) The furnisher, at the time furnishing occurs, makes a record of the furnishing in the manner required by Section 4146~~.

SEC. 10. Section 4146 of the Business and Professions Code is repealed.

~~4146. Any furnishing of a hypodermic syringe or hypodermic needle without a prescription shall, at the time of furnishing, be recorded in a book by the furnisher. The record of furnishing shall consist of the date and hour of the furnishing, the type or kind, size, and quantity of syringe or needle furnished, the purpose and use for which the needle or syringe was obtained, the signature of the furnisher, and the signature and address of the person to whom the needle or syringe was furnished. The record book shall be available for inspection by any authorized officer of the law.~~

SEC. 11. Section 4147 of the Business and Professions Code is amended to read:

4147. *(a) For purposes of this section, "playground" means any park or outdoor recreational area specifically designed to be used by children that has play equipment installed, or any similar facility located on public or private school grounds or on city or county parks.*

(b) Any hypodermic needle or syringe that is to be disposed of, shall be contained, treated, and disposed of, pursuant to Part 14 (commencing with Section 117600) of Division 104 of the Health and Safety Code.

(c) It shall be unlawful to discard or dispose of a hypodermic needle or syringe upon the grounds of a playground, a public beach, a public park, or any public or private elementary, vocational, junior high, or high school.

(d) A person who knowingly violates subdivision (c) is guilty of a misdemeanor, and upon conviction shall be punished by a fine or not less than two hundred dollars ($200) and not more than two thousand dollars ($2,000), or by imprisonment of up to six months, or by both that fine and imprisonment.

(e) Subdivision (c) shall not apply to the containment, treatment, and disposal of medical sharps waste from medical care or first aid services rendered on school grounds, nor to the containment, treatment, and disposal of hypodermic needles or syringes used for instructional or educational purposes on school grounds.

SEC. 12. Section 11364 of the Health and Safety Code is amended to read:

11364. *(a)* It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to the possession solely for personal use of supplies of up to 30 hypodermic needles or syringes acquired from authorized sources, including, but not limited to, pharmacies, hospitals, and public health clinics.

SEC. 13. Section 11364.5 of the Health and Safety Code is amended to read:

11364.5. (a) Except as authorized by law, ~~no~~ *a* person shall *not* maintain or operate ~~any~~ *a* place of business in which drug paraphernalia is kept, displayed or offered in any manner, sold, furnished, transferred or given away unless such drug paraphernalia is completely and wholly kept, displayed or offered within a separate room or enclosure to which persons under the age of 18 years not accompanied by a parent or legal guardian are excluded. Each entrance to such a room or enclosure shall be signposted in reasonably visible and legible words to the effect that drug paraphernalia is kept, displayed or offered in such room or enclosure and that minors, unless accompanied by a parent or legal guardian, are excluded.

(b) Except as authorized by law, no owner, manager, proprietor or other person in charge of any room or enclosure, within any place of business, in which drug paraphernalia is kept, displayed or offered in any manner, sold, furnished, transferred or given away shall permit or allow any person under the age of 18 years to enter, be in, remain in or visit such room or enclosure unless such minor person is accompanied by one of his or her parents or by his or her legal guardian.

(c) Unless authorized by law, no person under the age of 18 years shall enter, be in, remain in or visit any room or enclosure in any place of business in which drug paraphernalia is kept, displayed or offered in any manner, sold, furnished, transferred or given away unless accompanied by one of his or her parents or by his or her legal guardian.

(d) As used in this section, ''drug paraphernalia'' means all equipment, products, and materials of any kind which are intended for use or designed for use, in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance. ''Drug paraphernalia'' includes, but is not limited to, all of the following:

(1) Kits intended for use or designed for use in planting, propagating, cultivating, growing or harvesting of any species of

plant which is a controlled substance or from which a controlled substance can be derived.

(2) Kits intended for use or designed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances.

(3) Isomerization devices intended for use or designed for use in increasing the potency of any species of plant which is a controlled substance.

(4) Testing equipment intended for use or designed for use in identifying, or in analyzing the strength, effectiveness or purity of controlled substances.

(5) Scales and balances intended for use or designed for use in weighing or measuring controlled substances.

(6) Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose, and lactose, intended for use or designed for use in cutting controlled substances.

(7) Separation gins and sifters intended for use or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana.

(8) Blenders, bowls, containers, spoons, and mixing devices intended for use or designed for use in compounding controlled substances.

(9) Capsules, balloons, envelopes, and other containers intended for use or designed for use in packaging small quantities of controlled substances.

(10) Containers and other objects intended for use or designed for use in storing or concealing controlled substances.

(11) Hypodermic syringes, needles, and other objects intended for use or designed for use in parenterally injecting controlled substances into the human body.

(12) Objects intended for use or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as the following:

(A) Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls.

(B) Water pipes.

(C) Carburetion tubes and devices.

(D) Smoking and carburetion masks.

(E) Roach clips, meaning objects used to hold burning material, such as a marijuana cigarette that has become too small or too short to be held in the hand.

(F) Miniature cocaine spoons, and cocaine vials.

(G) Chamber pipes.

(H) Carburetor pipes.

(I) Electric pipes.

(J) Air-driven pipes.

(K) Chillums.

(L) Bongs.

(M) Ice pipes or chillers.

(e) In determining whether an object is drug paraphernalia, a court or other authority may consider, in addition to all other logically relevant factors, the following:

(1) Statements by an owner or by anyone in control of the object concerning its use.

(2) Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance.

(3) Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons whom he or she knows, or should reasonably know, intend to use the object to facilitate a violation of this section. The innocence of an owner, or of anyone in control of the object, as to a direct violation of this section shall not prevent a finding that the object is intended for use, or designed for use, as drug paraphernalia.

(4) Instructions, oral or written, provided with the object concerning its use.

(5) Descriptive materials, accompanying the object which explain or depict its use.

(6) National and local advertising concerning its use.

(7) The manner in which the object is displayed for sale.

(8) Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products.

(9) The existence and scope of legitimate uses for the object in the community.

(10) Expert testimony concerning its use.

(f) This section shall not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes drug paraphernalia described in paragraph (11) of subdivision (d) upon the prescription of a physician, dentist, podiatrist or veterinarian *or who sells hypodermic needles or syringes without a prescription pursuant to Section 4142 or 4145 of the Business and Professions Code*.

(2) Any physician, dentist, podiatrist or veterinarian who furnishes or prescribes drug paraphernalia described in paragraph (11) of subdivision (d) to his or her patients.

(3) Any manufacturer, wholesaler or retailer licensed by the California State Board of Pharmacy to sell or transfer drug paraphernalia described in paragraph (11) of subdivision (d).

(g) Notwithstanding any other provision of law, including Section 11374, violation of this section shall not constitute a criminal offense, but operation of a business in violation of the provisions of this section shall be grounds for revocation or nonrenewal of any license, permit, or other entitlement previously issued by a city, county, or city and county for the privilege of engaging in such business and shall be grounds for denial of any future license, permit, or other entitlement authorizing the conduct of such business or any other business, if the business includes the sale of drug paraphernalia.

SEC. 14. The Legislative Analyst shall review the available literature evaluating the following programs in regards to their public acceptance, efficacy, and cost: the New York State Department of Health Expanded Syringe Access Demonstration Program (ESAP) safety insert recommendations on safe syringe disposal, the Rhode Island State Department of Public Health-sponsored syringe disposal programs (Sharps Smart), and the San Francisco Safe Needle Disposal Program (SFSNDP). The Legislative Analyst shall also review recent literature on syringe disposal programs to identify other effective programs. The Legislative Analyst shall identify the most effective options for implementing a program in California, the approximate cost of implementing a program statewide, and a potential funding stream to support a program. On or before December 1, 2003, the Legislative Analyst shall report his or her findings to the committees of both houses of the Legislature with subject matter jurisdiction over health or criminal justice matters.

SEC. 15. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment N

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 57 **VERSION: AS AMENDED MARCH 10, 2003**

AUTHOR: BATES **SPONSOR: NONE**

RECOMMENDED POSITION: NONE

SUBJECT: MDMA

Existing Law:

1) Categorizes controlled substances into five schedules based on the risk of addiction and the existence of generally accepted medical use. (H&S 11054-11058)

2) Provides penalties up to and including incarceration in state prison for violations of laws relating to Schedule II controlled substances.

This Bill:

Categorizes MDMA (ecstasy) as a Schedule II controlled substance. (H&S 11055)

Comment:

1) Author's Intent. Existing federal law classifies MDMA as a Schedule I controlled substance. However, state law does not classify MDMA as a controlled substance and law enforcement cannot charge MDMA violations under state law.

2) Classification of Controlled Substances. Federal law spells out the criteria used to place substances in the appropriate schedule by the Attorney General of the United States. Those criteria are excerpted below:

a. Its actual or relative potential for abuse.
b. Scientific evidence of its pharmacological effect, if known.
c. The state of current scientific knowledge regarding the drug or other substance.
d. Its history and current pattern of abuse.
e. The scope, duration, and significance of abuse.
f. What, if any, risk there is to the public health.
g. Its psychic or physiological dependence liability.
h. Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Federal law provides added specific guidance on the placement of drugs into the five schedules, as follows:

Schedule I. -

- The drug or other substance has a high potential for abuse.

- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Schedule II. -
- The drug or other substance has a high potential for abuse.
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Abuse of the drug or other substances may lead to severe psychological or physical dependence.

Schedule III. -
- The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule IV. -
- The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Schedule V. -
- The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

2) State Law. California has its own controlled substance schedules which largely mirror the federal schedules. However, states can and do sometimes place substances into higher schedules (e.g., move from Schedule III to Schedule II) independent of federal action. It is unclear whether scheduling a drug at a lower schedule than specified in federal law is permissible. The question has been referred to board counsel.

3) Medical Use. This bill makes Ecstasy a Schedule II controlled substance. One of the factors to be considered in determining whether a drug should be classified as Schedule II is whether the drug or substance has a currently accepted medical use in treatment in the United States. Recently, the Federal Drug Administration (FDA) approved limited chemical trials of Ecstasy for the treatment of post-traumatic stress disorder.

4) MDMA. According to the United States Department of Justice Drug Enforcement Agency, MDMA is a close structural analog of amphetamine and methamphetamine. MDMA has both stimulant and hallucinogenic effects in humans. In the 1970's, MDMA was documented to produce permanent damage to serotonin pathways in the brains of rats and monkeys. Short-term, high-dose use of MDMA has produced incidences of

an amphetamine-like psychosis and, in some cases, severe hyperthermia which was unresponsive to medical intervention leading to death.

The subjective effects of MDMA in humans include a heightened sense of awareness as well as a feeling of increased empathy or emotional closeness to others. The production of MDMA in clandestine laboratories; its increasing abuse among young people; and evidence of adverse health effects, including brain damage, to emergency scheduling of MDMA into C1 of the Controlled Substance Act in 1985.

MDMA is usually taken orally in doses ranging from 50 to 150 mg. Doses of MDMA are often "piggy-backed" on each other in a series over just a few hours, leading to severe over-heating and cardiac emergencies which require medical intervention.

5) Analogs. Existing law applies the same penalties to drugs that are unscheduled "analogs" of drugs listed in the controlled substances schedules (H&S 11401). Ecstasy is unscheduled but has a chemical composition similar to methamphetamine, which is a Schedule II controlled substance. California courts have held that Ecstasy is an "analog" of methamphetamine, and offenses involving Ecstasy may be prosecuted as if it were methamphetamine. This bill would not affect the available penalties for the unlawful possession, possession for sale, and sale of Ecstasy. The penalties would be the same as those currently being imposed under the "analog" statute.

6) History.

Apr. 10	To inactive file on motion of Assembly Member Nunez.
Apr. 7	Read second time. To third reading.
Apr. 3	From committee: Do pass. (Ayes 25. Noes 0.) (April 2).
Mar. 11	Re-referred to Com. on APPR.
Feb. 27	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 0.) (February 25).
Jan. 13	Referred to Com. on PUB. S.
Dec. 9	Read first time.
Dec. 6	From printer. May be heard in committee January 5.
Dec. 5	Introduced. To print.

7) Support and Opposition

Support

Committee on Moral Concerns
County of San Diego
Los Angeles County District Attorney's Office
Peace Officers Research Association of California

Opposition

California Attorneys for Criminal Justice

AMENDED IN ASSEMBLY MARCH 10, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 57

Introduced by Assembly Member Bates

(Coauthors: Assembly Members Benoit, Daucher, Haynes, La Suer, Matthews, Maze, Mountjoy, Pacheco, Plescia, Runner, Vargas, and Wyland)

(Coauthors: Senators Ashburn, Denham, Knight, and Morrow)

December 5, 2002

An act to amend Section 11055 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 57, as amended, Bates. Controlled substances: Ecstasy (MDMA; XTC).

Existing law classifies controlled substances into 5 schedules and places the greatest restrictions and penalties on the use of those substances placed in Schedule I, including prohibiting the prescribing of any Schedule I controlled substance and requiring the prescription for any Schedule II controlled substance to be prepared in triplicate, as specified. The drug 3,4-Methylenedioxymethamphetamine, also known as MDMA, XTC, or Ecstasy, is a psychoactive drug possessing stimulant and hallucinogenic properties that is not classified within any of the schedules under the state controlled substances law, but is classified as a Schedule I drug under the federal controlled substances law.

This bill would classify the drug 3,4-Methylenedioxymethamphetamine within Schedule II of the state

controlled substances law. By expanding the scope of existing Schedule II crimes to also apply to this drug, this bill would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11055 of the Health and Safety Code is amended to read:

11055. (a) The controlled substances listed in this section are included in Schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium, opiate, and any salt, compound, derivative, or preparation of opium or opiate, with the exception of naloxone hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone hydrochloride), but including the following:

(A) Raw opium.

(B) Opium extracts.

(C) Opium fluid extracts.

(D) Powdered opium.

(E) Granulated opium.

(F) Tincture of opium.

(G) Apomorphine.

(H) Codeine.

(I) Ethylmorphine.

(J) Hydrocodone.

(K) Hydromorphone.

(L) Metopon.

(M) Morphine.

(N) Oxycodone.
(O) Oxymorphone.
(P) Thebaine.
(2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.
(3) Opium poppy and poppy straw.
(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.
(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).
(6) Cocaine, except as specified in Section 11054.
(7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.
(c) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:
(1) Alfentanyl.
(2) Alphaprodine.
(3) Anileridine.
(4) Bezitramide.
(5) Bulk dextropropoxyphene (nondosage forms).
(6) Dihydrocodeine.
(7) Diphenoxylate.
(8) Fentanyl.
(9) Isomethadone.
(10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).
(11) Levomethorphan.
(12) Levorphanol.
(13) Metazocine.

(14) Methadone.

(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(17) Pethidine (meperidine).

(18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(21) Phenazocine.

(22) Piminodine.

(23) Racemethorphan.

(24) Racemorphan.

(25) Sufentanyl.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Methamphetamine, its salts, isomers, and salts of its isomers.

(3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.

(4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.

(5) Phenmetrazine and its salts.

(6) Methylphenidate.

(7) 3,4-Methylenedioxymethamphetamine, including any trade name for that substance.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital.
(2) Pentobarbital.
(3) Phencyclidines, including the following:
(A) 1-(1-phenylcyclohexyl) piperidine (PCP).
(B) 1-(1-phenylcyclohexyl) morpholine (PCM).
(C) Any analog of phencyclidine which is added by the Attorney General by regulation pursuant to this paragraph.

The Attorney General, or his or her designee, may, by rule or regulation, add additional analogs of phencyclidine to those enumerated in this paragraph after notice, posting, and hearing pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The Attorney General shall, in the calendar year of the regular session of the Legislature in which the rule or regulation is adopted, submit a draft of a proposed bill to each house of the Legislature which would incorporate the analogs into this code. No rule or regulation shall remain in effect beyond January 1 after the calendar year of the regular session in which the draft of the proposed bill is submitted to each house. However, if the draft of the proposed bill is submitted during a recess of the Legislature exceeding 45 calendar days, the rule or regulation shall be effective until January 1 after the next calendar year.

(4) Secobarbital.
(5) Glutethimide.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

~~(A) Phenylacetone.~~ *Phenylacetone.* Some trade or other names: phenyl-2 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):
(A) 1-phenylcyclohexylamine.
(B) 1-piperidinocyclohexane carbonitrile (PCC).

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or

infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 186 **VERSION: AS INTRODUCED**

AUTHOR: CORREA **SPONSOR: CA OPTOMETRIC ASSOCIATION**

RECOMMENDED POSITION: NONE

SUBJECT: OPTOMETRISTS

Existing Law:

1) Permits optometrists to prescribe "therapeutic pharmaceutical agents" for the treatment of many eye diseases. (B&P 3041)

2) Defines optometrists as prescribers. (B&P 4170, Health & Safety Code 11150)

3) Specifies who may request and/or receive drug samples. (B&P 4061)

This Bill:

1) Adds optometrists to the list of persons who may receive shipments of dangerous drugs or dangerous devices without a prescriptions. (B&P 4059)

2) Permits physical therapists to furnish dangerous devices upon the prescription of an optometrist. (B&P 4059)

3) Adds optometrists to the list of prescribers of controlled substances. (B&P 4060)

4) Permits optometrists to request and receive drug samples. (B&P 4061)

Comment:

1) Author's Intent. To make a number of technical changes to pharmacy law to reflect the recently expanded scope of practice provided to optometrists. The changes would permit optometrists to order and receive drug samples, order and maintain drug stock (including controlled substances) in their offices and would eliminate a problem in current law that permits optometrists to prescribe controlled substances but does not allow patients to possess controlled substances prescribed by an optometrist.

2) Scope of Practice. Therapeutically certified optometrists have the authority to prescribe both topical and oral medications for the treatment of certain types of eye disease and ocular injuries. The drugs available to optometrists include controlled substances.

3) Physical Therapists? The bill permits optometrists to authorize the furnishing of a device by a physical therapist. It is unclear at this time what devices optometrists may prescribe that would be furnished by a physical therapist.

4) History.

Apr. 7	In Senate. Read first time. To Com. on RLS. for assignment.
Apr. 7	Read third time, passed, and to Senate. (Ayes 64. Noes 7. Page 945.)
Apr. 3	Read second time. To third reading.
Apr. 2	From committee: Do pass. (Ayes 13. Noes 0.) (April 1).
Mar. 20	Referred to Com. on B. & P.
Jan. 28	From printer. May be heard in committee February 27.
Jan. 27	Read first time. To print.

ASSEMBLY BILL No. 186

Introduced by Assembly Member Correa

January 27, 2003

An act to amend Sections 4059, 4060, and 4061 of the Business and Professions Code, relating to optometrists.

LEGISLATIVE COUNSEL'S DIGEST

AB 186, as introduced, Correa. Optometrists: dangerous drugs and devices.

Existing law, the Pharmacy Law, authorizes a manufacturer, wholesaler, or pharmacy to furnish a dangerous drug or dangerous device to a physician, dentist, podiatrist, and veterinarian without a prescription when accompanied by sale and purchase records. Existing law also permits these persons to possess a controlled substance when in properly labeled stocked containers, and also authorizes the distribution of a dangerous drug or device as a complimentary sample only upon the written request of these persons.

This bill would include optometrists in these provisions.

Existing law authorizes a pharmacist to furnish topical pharmaceutical agents to an optometrist.

The bill would instead authorize a pharmacist to furnish therapeutic pharmaceutical agents to an optometrist.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4059 of the Business and Professions Code is amended to read:

4059. (a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, *optometrist,* or veterinarian, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the board finds any dialysis drugs or devices distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State Department of Health Services. The physician prescribing the dialysis products shall submit proof satisfactory to the

manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist or may furnish ~~topical~~ *therapeutic* pharmaceutical agents authorized for use pursuant to ~~paragraph (5) of~~ subdivision ~~(a)~~ *(c)* of Section 3041 to an optometrist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy Examining Committee of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, *optometrist,* or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

(i) This section shall become operative on July 1, 2001.

SEC. 2. Section 4060 of the Business and Professions Code is amended to read:

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, *optometrist,* or veterinarian, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, physician, podiatrist, dentist, *optometrist,* veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.

SEC. 3. Section 4061 of the Business and Professions Code is amended to read:

4061. (a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, *optometrist,* or veterinarian. However, a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to a protocol described in Section 3502.1, may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725 or 3502.1, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, or physician assistant shall be defined within the standardized procedure, protocol, or practice agreement.

(b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, or physician assistant, if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

(c) Nothing in this section is intended to expand the scope of practice of a certified nurse-midwife, nurse practitioner, or physician assistant.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1196 **VERSION: AS AMENDED APRIL 10, 2003**

AUTHOR: MONTANEZ **SPONSOR: CA. COALITION OF NURSE PRACTITIONERS**

RECOMMENDED POSITION: NONE

SUBJECT: NURSE PRACTITIONERS

Existing Law:

1) Permits nurse practitioners to write prescriptions for Schedules III-V controlled substances under a protocol agreement with a physician. Schedule III controlled substances may only be prescribed under a patient specific protocol. (B&P 2836.1)

2) Permits physician assistants to write prescriptions for Schedule II-V controlled substances under a patient specific protocol agreement with a physician. (B&P 3502.1)

This Bill:

1) Permits nurse practitioners to prescribe Schedule II controlled substances under a patient specific protocol and after completing six months of training in ordering drugs under the supervision of a physician and completing a course in the pharmacology of the drugs to be prescribed. (B&P 2836.1)

2) Requires the nurse practitioner to notify the Board of Registered Nursing of the completion of the required training. (B&P 2836.1)

3) Requires the Board of Registered Nursing to issue a number to the nurse practitioner to be included on any prescription issued by the nurse practitioner. (B&P 2836.1)

4) Requires the Board of Registered Nursing to provide a list of these numbers to the Board of Pharmacy on request. (B&P 2836.1)

Comment:

1) Author's Intent. The California Association for Nurse Practitioners is sponsoring this bill to allow nurse practitioners (NPs) to furnish prescriptions for Schedule II controlled substances (CII) within standardized procedures approved by a physician. Current law allows midwifes and physician assistants to furnish CII medications, but NPs are only allowed to furnish prescriptions for Schedules III through V. The sponsors state that this has not only created an inequity amongst midlevel health care providers, but it has restricted the ability of NPs to provide quality care in a timely manner. The average number of years of post-secondary and graduate preparation to become a nurse practitioner is six years. NPs must first be a registered nurse and practice as a registered nurse to be eligible for entry into a NP program. There are 23 NP programs in California that award a Master's Degree in Nursing along with the NP certificate.

Safeguards within current law and this bill protecting against inappropriate prescribing of CIIs include:

1)The NP must have a furnishing number issued by BRN, which must be documented on all prescriptions he/she transmits.
2)The NP must register with the United Sates Drug Enforcement Administration;
3)The furnishing of controlled substances is done under a patient-specific protocol approved by the supervising physician.
4)The supervising physician may limit the types and quantities of scheduled medications the NP may furnish.
5)The furnishing of a CII may be prohibited in the patient-specific protocol by the supervising physician if not appropriate to that practice.
6)The protocol allowing the NP to furnish controlled substances must be available to the pharmacist dispensing the medication upon request.

Because of the escalation of medically underserved areas in California, the sponsor states it is imperative to the medical community to provide not only accessibility, but also a full-service quality of care to patients. However, chronic understaffing in areas where doctors are in short supply is continuously thwarting this effort, and NPs are often the first healthcare professionals administering to the patient's needs. In order to ensure that the best quality of care is being administered, NPs need to be given the flexibility to provide CII medications when necessary with strict oversight standards by a physician, BRN and the Drug Enforcement Agency.

2) Physician Assistants. Physician assistants have had Schedule II privileges since they were permitted to order medications by SB 1642 of 1994.

3) History

Apr. 10	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 8	From committee: Do pass, and re-refer to Com. on HEALTH. Re-referred. (Ayes 13. Noes 0.) (April 8).
Apr. 7	Re-referred to Com. on B. & P.
Apr. 3	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Mar. 20	Referred to Coms. on B. & P. and HEALTH
Feb. 24	Read first time.
Feb. 23	From printer. May be heard in committee March 25.
Feb. 21	Introduced. To print.

4) Support and Opposition.

Support
California Association for Nurse Practitioners
California Nurses Association California Psychiatric Association
Kaiser Permanente

Opposition
None

AMENDED IN ASSEMBLY APRIL 10, 2003

AMENDED IN ASSEMBLY APRIL 3, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 1196

Introduced by Assembly Member Montanez

February 21, 2003

An act to amend Section 2836.1 of the Business and Professions Code, relating to nurse practitioners.

LEGISLATIVE COUNSEL'S DIGEST

AB 1196, as amended, Montanez. Nurse practitioners: prescriptions.

Existing law, the Nursing Practice Act, licenses and regulates nurse practitioners and authorizes a nurse practitioner to furnish drugs or devices that are classified as Schedule III to Schedule V controlled substances under the California Uniform Controlled ~~Substance~~ *Substances* Act, subject to certain conditions. Existing law makes a violation of the act a misdemeanor.

This bill would expand these provisions to include drugs or devices that are classified as Schedule II controlled substances under the California Uniform Controlled Substances Act. The bill would establish additional requirements for a nurse practitioner who is authorized to furnish drugs or devices, including registering with the United States Drug Enforcement Administration. The bill would require the Board of Registered Nursing to certify and issue a nurse practitioner a number that the nurse practitioner must document on all prescriptions he or she transmits. The bill would require nurse

practitioners to complete a continuing education course ~~on~~ *including* Schedule II controlled substances based on standards developed by the board.

By increasing the scope of the Nursing Practice Act, the violation of which is a misdemeanor, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 2836.1 of the Business and Professions Code is amended to read:

2836.1. Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and his or her supervising physician and surgeon under any of the following circumstances:

(1) When furnished or ordered incidental to the provision of family planning services.

(2) When furnished or ordered incidental to the provision of routine health care or prenatal care.

(3) When rendered to essentially healthy persons.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or his or her designee.

(c) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs

or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

(f) (1) Drugs or devices furnished or ordered by a nurse practitioner may include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure.

(2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order. For Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(g) (1) The furnishing or ordering of drugs or devices by a nurse practitioner is conditional on the board issuing the nurse practitioner a number after he or she has successfully completed the requirements of paragraph (2). The nurse practitioner shall

include that number on all his or her transmittals of orders for drugs or devices. The board shall maintain a list of the nurse practitioners it has certified pursuant to this section and the number it has issued to each nurse practitioner. The board shall make the list available to the California State Board of Pharmacy upon its request. A nurse practitioner who is authorized to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.

(2) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed (1) at least six month's physician and surgeon-supervised experience in the furnishing or ordering of drugs or devices and (2) a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(3) Nurse practitioners who are certified by the board and hold an active furnishing number, who are authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration, shall complete, as part of their continuing education requirements, a course ~~on~~ *including* Schedule II controlled substances based on the standards developed by the board. The board shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term ''furnishing'' in this section, in health facilities defined in subdivisions (b), (c), (d), (e), and (i) of Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

(i) ''Drug order'' or ''order'' for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to ''prescription'' in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be

the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 292 **VERSION: AS INTRODUCED**

AUTHOR: SPEIER **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NONE

SUBJECT: PRESCRIPTION LABELS

Existing Law:

1) Requires the following elements on a prescription label:

a. drug name.
b. directions for the use of the drug.
c. name of the patient or patients.
d. name of the prescriber
e. date of issue.
f. name and address of the pharmacy
g. prescription number
h. strength of the drug
i. quantity of the drug
j. expiration date

2) Requires pharmacists to consult with the patient on any new prescription. (16CCR1707.2)

This Bill:

Requires each prescription label to include a color image of the pill dispensed. (B&P 4076)

Comment:

1) Author's Intent. The author introduced this bill in response to the continuing problem of medication errors. The bill proposes the color image of the pill as an additional check for both the pharmacist dispensing the medication and the patient taking the medication. The bill was introduced to stimulate discussion about how to decrease the incidence of wrong drug medication errors. The author indicates that one major chain currently includes a black and white image of the pill on the receipt for a prescription and that existing Oregon regulations require either an image or a written description of the pill on the prescription label. The author has not determined what the start-up costs would be to implement the bill's requirements.

2) Other Forms. The bill only contemplates drugs delivered in tablet or capsule form. A provision for exempting other forms or addressing the imaging of other forms of drugs (inhalants, injectables, eye drops, etc.) needs to be included.

3) History.

Apr. 8	Set for hearing April 28.
Apr. 7	Set, first hearing. Hearing canceled at the request of author.
Mar. 28	Set for hearing April 7.
Mar. 6	To Com. on B. & P.
Feb. 20	From print. May be acted upon on or after March 22.
Feb. 19	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 292

Introduced by Senator Speier

February 19, 2003

An act to amend Section 4076 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 292, as introduced, Speier. Pharmacy: prescription labels.

Under the Pharmacy Law, a pharmacist is required to dispense a prescription in a container that is correctly labeled. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

This bill would require the label to have a color image of the tablet or capsule of the drug. Because a knowing violation of the bill would be a misdemeanor, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber and, if applicable, the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) A color image of the tablet or capsule.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 490 **VERSION: AS AMENDED MARCH 27, 2003**

AUTHOR: ALPERT **SPONSOR: PUBLIC HEALTH INSTITUTE**

RECOMMENDED POSITION: NONE

SUBJECT: EMERGENCY CONTRACEPTION

Existing Law:

1) Permits pharmacists to dispense emergency contraception without a prescription if a protocol is established with a prescriber. (B&P 4052)

2) Requires that pharmacists to complete a training program in emergency contraception before dispensing emergency contraception without a prescription. (B&P 4052)

3) Requires pharmacists dispensing emergency contraception without a prescription to furnish the patient with a standard fact sheet on emergency contraception developed by the board. (B&P 4052)

This Bill:

1) Provides that a pharmacist may dispense emergency contraception either under a protocol with a physician or pursuant to a protocol approved by the board and the Medical Board. (B&P 4052)

2) Requires both boards to consult with the American College of Obstetricians and Gynecologists and other appropriate entities when approving the statewide protocol. (B&P 4052)

3) Requires the Medical Board to designate a licensed physician to serve as prescriber for the statewide protocol. (B&P 4052)

Comment:

1) Author's Intent. The author intends to further expand access to emergency contraception therapy. Two years after the passage of SB 1169 permitted pharmacists to dispense emergency contraception under protocol, there are still 12 counties where no pharmacist is dispensing emergency contraception under protocol and 85% of the protocols established are with prescribers affiliated with Planned Parenthood. Physicians are citing liability concerns when refusing to establish such a protocol with pharmacists. The establishment of a statewide protocol would eliminate this barrier to access. New Mexico has such a statewide protocol in place. The author anticipates amending the bill to assure broad participation in the protocol development process by physician organizations.

2) Emergency Contraception. Emergency contraception (EC) drug therapy, commonly referred to as the "morning after pill" are hormone pills that when taken within 72 hours of unprotected intercourse, reduce the chance of a woman becoming pregnant by about 75 percent. The hormones are regular birth control pills containing estrogen and progestin, taken in two doses. In California and Washington, there is also available an EC pill known as "Plan B" made from synthetic progestin. The EC pills provide a short, high burst of hormone exposure that disrupts the hormone patterns essential for pregnancy. The EC pills reduce the hormone release from the ovary and the development of the uterine lining is disturbed, the disruptions are temporary, however, lasting only a few days. Depending on the time during the menstrual cycle when the EC pills are taken, they prevent pregnancy by inhibiting or delaying ovulation, or altering the lining of the uterus thereby inhibiting implantation of a fertilized egg. The EC pills can also prevent sperm from fertilizing an egg. EC pills do not cause an abortion. Because implantation occurs five to seven days after fertilization, EC pills work before implantation and not after a woman is already pregnant.

3) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation.

4) Related Legislation. Senator Jackie Speier introduced Senate Bill 545 in the current legislative session which prohibits pharmacists from charging a consultation fee for emergency contraception that exceeds the dispensing fee provided by Medi-Cal.

5) New Mexico. New Mexico has adopted a statewide protocol for pharmacists dispensing emergency contraception as proposed by this bill. That protocol was developed by the state board of pharmacy in conjunction with the state medical board and the state nursing board. A copy of that protocol is attached for your reference.

6) History.

Apr. 3	From committee: Do pass, but first be re-referred to Com. on B. & P. (Ayes 7. Noes 1. Page 451.) Re-referred to Com. on B. & P.
Mar. 27	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 13	Set for hearing April 2.
Mar. 13	To Coms. on H. & H.S. and B. & P.
Feb. 21	From print. May be acted upon on or after March 23.
Feb. 20	Introduced. Read first time. To Com. on RLS. for assignment. To print.

7) Support & Opposition

Support
Pharmacy Access Partnership (sponsor)
American College of Obstetricians and Gynecologists
California Abortion and Reproductive Rights Action League
California Commission on the Status of Women
California Family Health Council
California Medical Association
California Women Lawyers
Institute for Health Policy Studies
Planned Parenthood
Los Angeles Planned Parenthood Affiliates of California
Public Health Institute
San Francisco Health Plan
Six Rivers Planned Parenthood

Three individual

Oppose
None

AMENDED IN SENATE MARCH 27, 2003

SENATE BILL No. 490

Introduced by Senator Alpert

February 20, 2003

An act to amend Section 4052 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 490, as amended, Alpert. Pharmacy: prescriptions.

Existing law regulates the practice of pharmacy by the California State Board of Pharmacy. Under existing law, a pharmacist may not, in general, furnish a dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. However, existing law authorizes a pharmacist to initiate emergency contraception drug therapy in accordance with standardized protocols developed by the pharmacist and an authorized prescriber acting within his or her scope of practice.

This bill would also authorize a pharmacist to ~~initiate~~ *furnish* emergency contraception drug therapy in accordance with a standardized procedure or protocol approved by ~~the board~~ *both the board and the Medical Board of California, in consultation with specified entities. The bill would require a pharmacist to receive specified training prior to furnishing emergency contraception drug therapy.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that

health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) ~~Initiate~~ *Furnish* emergency contraception drug therapy in accordance with either of the following:

(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(B) A standardized procedure or protocol approved by ~~the board.~~

~~Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception, which includes, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation.~~ *both the board and Medical Board of California, in consultation with the American College of Obstetricians and Gynecologists, and other appropriate entities. For purposes of a standardized procedure or protocol under this subparagraph, the Medical Board of California shall designate an authorized prescriber who is acting within his or her scope of practice.*

(9) Prior to furnishing emergency contraception drug therapy authorized under paragraph (8), a pharmacist shall receive training regarding the appropriate use and indications for emergency contraception.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A)

successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 506 **VERSION: AS INTRODUCED**

AUTHOR: SHER **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NONE

SUBJECT: ANIMAL DRUGS

Existing Law:

1) Permits the board to issue a license to a wholesaler as a veterinary food-animal drug retailer (vet retailer). (B&P 4053)

2) Permits vet retailers to dispense veterinary prescriptions for food animals directly to the client without a pharmacist. (B&P 4053)

3) Requires vet retailers to have a qualified exemptee on the premises when dispensing food animal drugs. (B&P 4053)

4) Specifies the training required for vet retailer exemptees. (16CCR1780.1)

This Bill:

Prohibits vet retailers from dispensing injectable or oral antibiotics. (B&P 4053)

Comment:

1) Author's Intent. The author introduced this bill to address the issue of the extensive use of antibiotics in food-animals and how these practices contribute to antibiotic resistance. The bill is in a very early form and the author expects substantial amendments focusing on how to improve the handling and dispensing of drugs by veterinary food-animal drug retailers. As written, the bill would require that antibiotics for food-animals be labeled and distributed by either a pharmacy or a veterinarian instead of a veterinary food-animal drug retailer.

2) Antibiotic Resistance. According to the Food and Drug Administration (FDA), disease-causing microbes that have become resistant to drug therapy are an increasing public health problem. Tuberculosis, gonorrhea, malaria, and childhood ear infections are just a few of the diseases that have become hard to treat with antibiotic drugs. The increase in antibiotic resistance is due largely to the increasing use of antibiotics. The FDA also notes the following:

- Though food-producing animals are given antibiotic drugs for important therapeutic, disease prevention or production reasons, these drugs have the downside of potentially causing microbes to become resistant to drugs used to treat human illness, ultimately making some human sicknesses harder to treat.
- About 70 percent of bacteria that cause infections in hospitals are resistant to at least one of the drugs most commonly used to treat infections.

- Some organisms are resistant to all approved antibiotics and must be treated with experimental and potentially toxic drugs.
- Some research has shown that antibiotics are given to patients more often than guidelines set by federal and other healthcare organizations recommend.

3) History.

Apr. 8	Set for hearing April 28.
Mar. 6	To Com. on B. & P.
Feb. 21	From print. May be acted upon on or after March 23.
Feb. 20	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 506

Introduced by Senator Sher

February 20, 2003

An act to amend Section 4053 of the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 506, as introduced, Sher. Veterinary food-animal drug retailers.

The Pharmacy Law makes it unlawful for any person other than a pharmacist to compound or dispense a dangerous drug or device, or to compound or dispense a prescription. Existing law provides exemptions from this prohibition for specified persons, including a veterinary food-animal drug retailer under certain circumstances.

This bill would prohibit a veterinary food-animal drug retailer from applying for an exemption to distribute oral or injectable antibiotics.

Because violations of this bill would be a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4053 of the Business and Professions Code is amended to read:

4053. (a) Subdivision (a) of Section 4051 shall not apply to a manufacturer, veterinary food-animal drug retailer, or wholesaler if the board shall find that sufficient, qualified supervision is employed by the manufacturer, veterinary food-animal drug retailer, or wholesaler to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) An individual employed by a manufacturer, veterinary food-animal drug retailer, or wholesaler may apply for an exemption from Section 4051. In order to obtain and maintain that exemption, the individual shall meet the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of state and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of state and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may, by regulation, require training programs to include additional material.

(6) The board shall not issue a certificate of exemption until the applicant provides proof of completion of the required training to the board.

(c) The manufacturer, veterinary food-animal drug retailer, or wholesaler shall not operate without a pharmacist or an individual in possession of a certificate of exemption on its premises.

(d) Only a pharmacist or an individual in possession of a certificate of exemption shall prepare and affix the label to veterinary food-animal drugs.

(e) Notwithstanding any other provision of law, a veterinary food-animal drug retailer may not apply for an exemption to distribute injectable or oral antibiotics.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment O

State of California Department of Consumer Affairs

Memorandum

To: Board Members Date: April 9, 2003

From: Paul Riches
Legislative Analyst

Subject: Regulations Update

Recently Approved

Section 1717 (e) – Delivery of Medications
Summary: This regulation will eliminate the waiver process established by 1717(e). This waiver process permits pharmacies to depot drugs for delivery to patients at non-pharmacy locations. Instead, the regulation will permit pharmacies to depot drugs at any location where the patient receives health care services.
Status: Effective March 12, 2003.

Section 1720.4 – Foreign Graduates
Summary: This regulation will specify the procedure for foreign graduates who cannot obtain verifiable transcripts to become eligible to take the pharmacist license examination.
Status: Effective March 13, 2003.

Section 1745 – Partial Filling of Schedule II Prescriptions
Summary: This regulation will make the partial fill regulation consistent with recent statutory changes to Schedule II prescription requirements.
Status: Effective March 12, 2003.

Pending Regulations

Section 1732.05 – Continuing Education
Summary: This regulation will recognize continuing education credits approved by other California health professions licensing boards.
Status: 15 day comment period closed on March 28, 2003.

Section 1751 – Sterile Compounding
Summary: This regulation will establish guidelines for the compounding of sterile drug products.
Status: The 45 day comment period ended on April 7, 2003.

Section 1775 – Citation and Fine

Summary: This regulation designates the executive officer as the issuing authority for citations and fines.
Status: The 45 day comment period ended on April 7, 2002.

Awaiting Notice

Section 1707.5 – Hospital Central Fill
Summary: This regulation will permit central refill operations for hospitals.
Status: Conducted informational hearing at October 2002 board meeting.

Section 1709.1 - Pharmacist-in-Charge at Two Locations
Summary: This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.
Status: None

Section 1715 – Pharmacy Self Assessment
Summary: This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.
Status: None.

Section 1717.4 and 1717.2 – Electronic Prescriptions & Electronic Records
Summary: This regulation will make any needed changes to board regulations to conform to Assembly Bill 2240 and require that pharmacists confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. It will also repeal section 1717.2. The notice to consumers required by this section has been superseded by amendments to California law that substantially strengthened privacy protections.
Status: None

Section 1717.4 – Authentication of Electronic Prescriptions
Summary: This regulation will require pharmacists to authenticate electronic prescriptions.
Status: None

Section 1764 – Wholesaling
Summary: This regulation will impose dollar volume limits on wholesale drug transfers by pharmacies, impose dollar volume limits on transfers between wholesalers, and require pedigrees for drug shipments under specified circumstances.
Status: The Enforcement Committee conducted an informational hearing on this proposal at its December 2002 meeting.

Section 1793.3 – "Clerk-Typist" Ratio
Summary: This regulation will eliminate the clerk/typist ratio.
Status: None.

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Attachment P

Legislation and Regulation

Goal

Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Implementation Responsibility

Legislation and Regulation Committee and Staff

Strategic Objectives	Timeline
1. Secure the passage of legislation extending the board's sunset date. ▪ Submitted the Sunset Review Report to the Joint Legislative Sunset Review Committee (JLSRC) on September 3, 2002. ▪ Provided testimony before the JLSRC on November 19, 2002. ▪ The JLSRC voted to extend the board for four years on April 7, 2003.	September 2003
2. Revise the Notice to Consumers required by 16 CCR section 1707.2 ▪ Regulation approved by OAL on August 8, 2002.	September 2002
3. Promulgate a regulation protecting financial records submitted to the board as part of a site license application as confidential documents.	July 2003
4. Promulgate a regulation to permit pharmacies to depot drugs for delivery to patients at non-pharmacy locations where the patient receives health care services. ▪ Notice of Proposed Action published August	July 2003

Strategic Objectives	Timeline
2, 2002. ▪ Board approved the regulation at the October 2002 board meeting. ▪ Rulemaking file submitted for review by the Department of Consumer Affairs, December 2002. ▪ Rulemaking file was approved by OAL and was effective on March 12, 2003.	
5. Promulgate expanded citation and fine regulations permitting citation and fine for violations of the Confidentiality of Medical Information Act and for Internet violations. ▪ Rulemaking file submitted to OAL on September 13, 2002. ▪ Rulemaking approved by the Office of Administrative Law on October 23, 2002.	August 2002
6. Revise regulations concerning electronic prescribing to conform to AB 2240, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity.	July 2003
7. Initiate regulations to specify the procedure for foreign pharmacy graduates who cannot obtain transcripts to become eligible to take the pharmacist licensure examinations. ▪ Rulemaking notice published on August 2, 2002. ▪ Board approved the regulation at the October 2002 board meeting. ▪ Rulemaking file submitted for review by the Department of Consumer Affairs, December 2002. ▪ Rulemaking file was approved by OAL and	July 2003

Strategic Objectives	Timeline
became effective March 13, 2003.	
8. Conform board regulations regarding partial filling of Schedule II substances with statutory changes to Schedule II prescription requirements. ▪ Notice of Proposed Action published August 2, 2002. ▪ Board approved the regulation at the October 2002 board meeting. ▪ Rulemaking file submitted for review by the Department of Consumer Affairs, December 2002. ▪ Rulemaking file was approved by OAL and was effective on March 12, 2003.	July 2003
9. Promulgate a regulation for standards for sterile compounding of drug products. ▪ Notice of Proposed Action published August 30, 2002. ▪ Regulation hearing held at the October 2002 board meeting. ▪ Regulation workshop on revised standards held on December 5, 2002. ▪ Revised regulation noticed on February 21, 2003 and the 45-day comment period closed on April 7, 2003.	January 2003
10. Revise regulations to make technical corrections required by recent legislation. ▪ Section 100 rulemaking was approved in September 2002.	January 2003
11. Promulgate a regulation recognizing continuing education credits for courses approved by other health care licensing boards.	March 2003

Strategic Objectives	Timeline
Informational hearing conducted on September 24, 2002. ▪ Rulemaking notice was published on October 31, 2002. ▪ Board adopted the regulation at the January 22, 2003 board meeting.	
12. Hold two public meetings annually to develop board proposals for legislation and regulation changes, and to recommend policy positions on introduced legislation. ▪ Public meeting held on October 24, 2002 in conjunction with quarterly board meeting. ▪ Public meeting held on March 27, 2003 in the board's Sacramento office.	October 2002 and March 2003

Ongoing Objectives

13. Promote the board's policy positions on pending legislation.

The board supported the following legislation in 2002:

AB 269 (Correa) Support
AB 2045 (Matthews) Support
AB 2191 (Migden) Support
AB 2935 (Strom-Martin) Support
SB 1558 (Figueroa) Support
SB 1750 (Speier) Support If Amended
SB 1785 (Vasconcellos) Support
SB 2018 (Figueroa) Support
SB 2026 (Senate Business and Professions Committee) Support

The board supported the following legislation in 2003:

SB 151 (Burton) Support

14. Advocate the board's role in promoting public protection regarding pharmacists' care and dispensing of dangerous drugs and devices.

    - Board members participated in medication safety forum on September 26, 2002.
    - Staff made presentation to UCSF pharmacy students on the board's role and contemporary issues in pharmacy law on February 18, 2003.
    - Board president moderated discussion on adopting the NAPLEX at UCSF School of Pharmacy.
    -

15. Pursue legislation and regulations that provide consumer protection while minimizing intrusion on the marketplace, to the extent possible.

    - Sponsored AB 2655 (Matthews) to extend CURES for five years and make profile data available to practitioners.
    - AB 2655 (Matthews) signed by the Governor on August 31, 2002.
    - Sponsored provisions in SB 361 to provide the board will three enforcement tools (order of correction, letter of admonishment, mandatory continuing education).

16. Undertake continual review of statutes and regulations to assure they reflect actual pharmacy practice and provide a consumer protection focus.

    - Section 100 update of Title 16, Division 17 approved September 2002.
    - Sponsored provisions in the annual omnibus bill (SB 2026) to update the Pharmacy Law and the California Uniform Controlled Substances Act.
    - Sponsored provisions in the board's sunset review bill (SB 361) to make a number of technical corrections to the Pharmacy Law.

17. Promote and advocate legislative or regulatory changes to keep pharmacy requirements current and consistent with the board's strategic purpose.

    - Sponsored provisions in SB 361 to revise the qualifications for becoming licensed as a pharmacy technician.

18. Participate in local, state and national forums to advocate the public interest in emerging policy and regulatory areas regarding pharmacists' care and the dispensing of dangerous drugs and devices.

    - Staff participated in the annual forum for regulators and educators at the NACDS Pharmacy Technology Conference on September 10, 2002.

    - Staff presented the proposed sterile compounding standards and quality assurance program regulations to the National Home Infusion Association on September 17, 2002.

    - Staff and Board Members made a presentation regarding the quality assurance program regulation to the CPhA Western Pharmacy Education Faire on September 27, 2002.

    - The board staffed an information booth at the CPhA Western Pharmacy Education Faire.

    - Staff made a presentation to the Los Angeles District Attorney on the CURES program October 4, 2002.

    - The board staffed an information booth at the CSHP Seminar in Anaheim October 3-6.

    - The Board President addressed the National Association of Boards of Pharmacy mid-year conference in November 2002 regarding quality assurance.

    - The board president participated in the National Association of Boards of Pharmacy HIPAA task force.

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Attachment Q

California State Board of Pharmacy
Strategic Plan

Legislation and Regulation

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1:	**Promote or advocate 25 legislative changes to keep pharmacy law requirements current and consistent with the board's mission by June 30, 2005.**
Tasks:	1. Secure extension of board's sunset date. 2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. 3. Sponsor legislation to add enforcement options for non-compliance issues. 4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. 5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices.

Objective 3.2:	**Promulgate 15 regulation changes to keep pharmacy law current and consistent with the board's mission by June 30, 2005.**
Tasks:	1. Strengthen standards for compounding sterile injectable drug products. 2. Authorize the executive officer the authority to issue citations and fines. 3. Eliminate the clerk typist ratio. 4. Allow pharmacists to be pharmacist-in-charge of two locations. 5. Update pharmacy Self-Assessment document. 6. Allow central filling by hospital pharmacies. 7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity.

Objective 3.3:	**Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.**

Tasks:	1. Evaluate electronic prescribing laws involving controlled substances. 2. Evaluate the prescribing and dispensing of veterinary drugs. 3. Evaluate group dispensing by prescribers.

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Attachment R

MEETING MINUTES
LEGISLATION AND REGULATION COMMITTEE
DATE: MARCH 27, 2003
LOCATION: 400 R STREET, SUITE 4070
SACRAMENTO, CA 95814

BOARD MEMBERS PRESENT:

STEVE LITSEY
ANDREA ZINDER

BOARD STAFF PRESENT:

PATRICIA HARRIS
VIRGINIA HEROLD
PAUL RICHES

The meeting was convened at 10:00 a.m.

I. Bills of Interest to the Board of Pharmacy.

Assembly Bill 57

The committee discussed the measure and declined to take a position on the measure as it is not furthering existing strategic objectives or central to board operations.

Assembly Bill 103.

The committee is sympathetic with the desire to decrease drug costs and open drug marketing practices to greater public scrutiny. However, the bill as currently drafted imposes a significant new programmatic responsibility on the board without providing additional resources to implement this new program. In addition, the bill requires substantial amendments to clarify the program requirements and to allow for effective implementation. Accordingly, the committee recommends an oppose unless amended position. The recommended amendments would provide for either General Fund or non-profit financial support of the program and makes a number of other changes required for effective program implementation. The proposed amendments are attached to the analysis on this bill.

Assembly Bill 186

The committee discussed the measure and declined to take a position on the measure as it is not furthering existing strategic objectives or central to board operations.

Assembly Bill 261.

The committee recommends a support position on Assembly Bill 261. The public health threat posed by backroom clinics warrants granting prosecutors the opportunity to charge these cases as felonies.

Assembly Bill 521.

The committee recommends a support if amended position on Assembly Bill 521 because it will provide consumers with valuable drug information in an accessible format. The committee recommends amendments that would specify a minimum type size and defer implementation to allow adequate time for pharmacies to make the required system changes. The proposed amendments are attached to the analysis on this bill.

Assembly Bill 746.

The committee recommends a support position on Assembly Bill 746 because it grants the board greater authority to take disciplinary action against licensee convicted of Medi-Cal fraud.

Assembly Bill 1196

The committee discussed the measure and declined to take a position on the measure as it is not furthering existing strategic objectives or central to board operations.

Assembly Bill 1363.

The committee recommends a support position on Assembly Bill 1363 because it will expand access to clean needles and syringes. The board has supported such legislation in the past based on the public health benefit of these proposals.

Assembly Bill 1460.

The committee recommends a support position on Assembly Bill 1460 because it intends to provide pharmacists with greater ability to manage patients drug therapy.

Senate Bill 250

The committee discussed the measure and declined to take a position on the measure as it is not furthering existing strategic objectives or central to board operations.

Senate Bill 292

The committee discussed the measure and declined to take a position until the author clarified the intent of the bill.

Senate Bill 393.

The committee recommends a support if amended position on Senate Bill 393 because it implements much of the board's existing policy supporting tech check tech in hospitals. The committee seeks an amendment specifying the training required for pharmacy technicians in tech check tech programs in statute.

Senate Bill 490
The committee declined to take a position because substantial amendments are expected. The board will have an opportunity to evaluate those amendments at the April 29, 2003 board meeting when more complete information is available.

Senate Bill 506

The committee declined to take a position because substantial amendments are expected. The board will have an opportunity to evaluate those amendments at the April 29, 2003 board meeting when more complete information is available.

Senate Bill 545.

The committee recommends an oppose unless amended position on Senate Bill 545 because it deletes the training requirement for dispensing emergency contraception under protocol and inappropriately limits pharmacists' judgment regarding appropriate patient consultation. The committee also expressed concern that the bill fails to recognize the practice of pharmacy outside the four walls of a pharmacy. The committee recommends amendments restoring the training requirements and deleting the restriction on patient consultation.

Senate Bill 774.

The committee recommends a support position on Assembly Bill 1363 because it will expand access to clean needles and syringes. The board has supported such legislation in the past based on the public health benefit of these proposals.

II. SB 175 – Veterinary Drugs.

Senate Bill 175.

The committee recommends a support if amended position on Senate Bill 175 because it clarifies the board's regulatory authority over veterinary drugs. The recommended amendments make technical changes to the bill.

III. Omnibus Item.

That the board sponsor the addition of section 4106 in the annual omnibus bill.

The committee is suggesting this language to reduce workload associated with providing license verifications to interested parties. By allowing license verifications from the board's to be accepted by those needing to verify licensure, fewer verification requests will be submitted to

board staff. This is particularly of concern for wholesalers wishing to ship to newly licensed pharmacies.

IV. Regulations Update.

A. The committee was provided the following update on pending regulations.

V. Strategic Plan Review

The committee reviewed and approved the revised format for the board's strategic plan as it relates to the Legislation and Regulation Committee.

VI. Future Meetings.

The committee agreed to conduct its next meeting on June 25, 2003 at 9 a.m.

VII. Adjournment

The committee adjourned at 1:45 p.m.